UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

IN RE BYSTOLIC ANTITRUST LITIGATION	
This Document Relates To:	20-cv-5735 (LJL)
All Direct Purchaser Actions *CVS Action* (No. 20-cv-10087) *Walgreen Action* (No. 20-cv-9793) All End-Payor Actions	OPINION AND ORDER

LEWIS J. LIMAN, United States District Judge:

This civil antitrust action alleges an illegal scheme to delay competition from generic versions of Bystolic (nebivolol hydrochloride), a prescription medication approved by the U.S. Food and Drug Administration to treat high blood pressure.

Plaintiffs are: a putative class of direct purchasers of Bystolic and generic versions of Bystolic ("Direct Purchaser Plaintiffs");[1] a putative class of indirect purchasers, including consumers, health insurers, and welfare plans, of Bystolic and generic versions of Bystolic ("End-Payor Plaintiffs");[2] and several retail chains that bring individual lawsuits as assignees of direct purchasers ("Retailer Plaintiffs")[3] (collectively, "Plaintiffs"). Defendants are the

[1] Direct Purchaser Plaintiffs are J M Smith Corporation d/b/a Smith Drug Company and KPH Healthcare Services, Inc. a/k/a Kinney Drugs, Inc., on behalf of themselves and all others similarly situated.

[2] End Payor Plaintiffs are the Mayor and City Council of Baltimore ("City of Baltimore"), UFCW Local 1500 Welfare Fund ("Local 1500"), Teamsters Western Region & Local 177 Health Care Plan ("Local 177"), Fraternal Order of Police, Miami Lodge 20, Insurance Trust Fund ("FOP"), Law Enforcement Health Benefits, Inc. ("LEHB"), Teamsters Local No. 1150 Prescription Drug Benefit Plan ("Local 1150"), and Teamsters Local 237 Welfare Fund and Teamsters Local 237 Retirees' Benefit Fund ("Local 237"), on behalf of themselves and all others similarly situated.

[3] Retailer Plaintiffs are CVS Pharmacy, Inc., Rite Aid Corporation, Rite Aid Hdqtrs. Corp., Walgreen Co., The Kroger Co., Albertsons Companies, Inc., and H-E-B, L.P. The first three

manufacturers and marketers of Bystolic (collectively referred to as "Forest")[4] and their generic-drug competitors ("Generic Defendants")[5] (collectively, "Defendants"). Generic Defendants include Hetero, Torrent, Alkem, Indchemie, Glenmark, Amerigen, and Watson.

Plaintiffs allege that Forest agreed to pay Generic Defendants to drop their challenges to a Bystolic patent and to delay launching less expensive, competing generic versions of Bystolic for years. Direct Purchaser Plaintiffs bring a class action complaint ("Direct Purchaser Plaintiffs' Complaint" or "DPP Complaint") and Retailer Plaintiffs bring complaints ("Retailer Plaintiffs' Complaints") against Defendants, seeking damages under federal antitrust law. Second Consolidated and Amended Class Action Complaint, Dkt. No. 250 ("DPP Compl."); Second Amended Complaint, *CVS Action*, 20-cv-10087 (S.D.N.Y.), ECF No. 35; Second Amended Complaint, *Walgreen Action*, 20-cv-9793 (S.D.N.Y.), ECF No. 34. End-Payor Plaintiffs bring a class action complaint ("End-Payor Plaintiffs' Complaint" or "EPP Complaint") against Defendants under state antitrust and consumer-protection laws and for

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plaintiffs are the plaintiffs in *CVS Pharmacy, Inc. et al v. AbbVie Inc. et al* ("*CVS Action*"), 20-cv-10087 (S.D.N.Y.), and the latter group of plaintiffs are the plaintiffs in *Walgreen Co. et al v. AbbVie Inc. et al* ("*Walgreen Action*"), 20-cv-9793 (S.D.N.Y.).

[4] "Forest" refers collectively to: Forest Laboratories, Inc., Forest Laboratories Holdings, Ltd., Forest Laboratories, LLC, and Forest Laboratories Ireland Ltd.; AbbVie, Inc. ("AbbVie"); and Allergan, Inc., Allergan Sales, LLC, and Allergan USA, Inc. (collectively, "Allergan").

[5] Generic Defendants are: Hetero USA Inc., Hetero Labs Ltd., and Hetero Drugs Ltd. (collectively, "Hetero"); Torrent Pharmaceuticals Ltd. and Torrent Pharma Inc. (collectively, "Torrent"); Ascend Laboratories, LLC and Alkem Laboratories Ltd. (collectively, "Alkem"); Indchemie Health Specialties Private Ltd. ("Indchemie"); Glenmark Generics Inc., USA, Glenmark Generics Ltd., Glenmark Pharmaceuticals Ltd., and Glenmark Pharmaceuticals S.A. (collectively, "Glenmark"); ANI Pharmaceuticals, Inc., Amerigen Pharmaceuticals, Inc., and Amerigen Pharmaceuticals, Ltd. (collectively, "Amerigen"); Teva Pharmaceuticals Industries Ltd. ("Teva Israel"); Watson Laboratories, Inc. (NV), Watson Laboratories, Inc. (DE), Watson Laboratories, Inc. (NY), Watson Laboratories, Inc. (CT), Watson Pharma, Inc., Watson Pharmaceuticals Inc., Actavis, Inc., and Teva Pharmaceuticals USA, Inc. (collectively with Teva Israel, "Watson").

injunctive relief under federal antitrust law. End-Payor Plaintiffs' Consolidated Amended Class Action Complaint, Dkt. No. 251 ("EPP Compl.").

Pending before the Court are four related motions to dismiss. All Defendants move to dismiss Direct Purchaser and Retailer Plaintiffs' Complaints for failure to state a claim, Dkt. No. 267, and move to dismiss End-Payor Plaintiffs' Complaint for failure to state a claim, Dkt. No. 271, pursuant to Federal Rule of Civil Procedure 12(b)(6). Defendant Teva Israel also moves pursuant to Federal Rule of Civil Procedure 12(b)(2) to dismiss the claims against it for lack of personal jurisdiction. Dkt. No. 260. And a group of twenty-eight Defendants not at home in New York ("Nonresident Defendants")[6] move pursuant to Federal Rule of Civil Procedure 12(b)(2) to dismiss for lack of personal jurisdiction the End-Payor Complaint's ninety-nine non-New York, state-law claims. Dkt. No. 265.

BACKGROUND

On each of the four motions to dismiss, the Court accepts as true the allegations of the relevant complaints, and the documents incorporated by reference.[7]

I. Overview of the Alleged Scheme

From October 2012 through November 2013, Forest allegedly entered into a series of reverse-payment deals (also known as "pay for delay" deals) with Generic Defendants under which each Generic Defendant (1) agreed not to compete with Forest or enter the market with its generic version of Bystolic prior to September 17, 2021 (three months before patent expiration),

[6] Nonresident Defendants include all Defendants except for Watson Laboratories, Inc. (NY), Forest Laboratories, Inc., and the latter's successors—Forest Laboratories, LLC and Allergan Sales, LLC.

[7] This opinion cites the DPP Complaint as the other plaintiffs' complaints are substantially identical.

unless another Generic Defendant entered that market earlier; and in exchange (2) received "side-deals" and cash payments from Forest. DPP Compl. ¶ 3.

Earlier, Forest had sued each Generic Defendant for patent infringement. *Id.* ¶ 4. Although Generic Defendants would have allegedly succeeded in the patent litigation, as Forest's claim was weak, and they would have been ready to launch their generic versions of Bystolic well before September 17, 2021, Generic Defendants agreed to side deals with Forest to end the patent fight. *Id.* ¶¶ 5–7. Each Generic Defendant agreed to stay off the market until September 17, 2021 in exchange for a share of Forest's monopoly profits in the form of reverse payments. *Id.* ¶¶ 6–7. In other words, but for these payments, Generic Defendants would have launched their generic products earlier and Plaintiffs would have paid substantially less for nebivolol hydrochloride, i.e., Bystolic. *Id.* ¶ 26. As a result, the entry of less expensive, generic versions of Bystolic was delayed, the price of nebivolol hydrochloride was fixed at the price of Bystolic, and 100% of the United States market for nebivolol hydrochloride was allocated to Forest until September 17, 2021. *Id.* ¶ 28.

These allegations are discussed in greater detail next.

II. Relevant Regulatory Framework for Generic Drugs

Under the Federal Food, Drug, and Cosmetic Act ("FDCA"), manufacturers of a new drug must obtain approval from the U.S. Food and Drug Administration ("FDA") by filing a New Drug Application ("NDA"). 21 U.S.C. §§ 301–392; DPP Compl. ¶ 93. Among the information contained in an NDA is information on applicable patents. *Id.* § 355(a), (b); DPP Compl. ¶ 93. When the FDA approves a drug manufacturer's NDA, the manufacturer may list certain patents in the "Approved Drug Products with Therapeutic Equivalence Evaluations" (known as the "Orange Book"). DPP Compl. ¶ 94. The listed patents are those that could

reasonably be asserted against a generic manufacturer of the branded drug before the patents expire. *Id.*

Manufacturers of generic versions of a branded drug may receive FDA approval through a different pathway. The Hatch-Waxman Amendments, enacted in 1984, simplified the regulatory hurdles for prospective generic manufacturers by eliminating the need to file lengthy and costly NDAs. *See* Drug Price Competition and Patent Term Restoration Act, Pub. L. No. 98-417, 98 Stat. 1585 (1984); DPP Compl. ¶ 96. Instead, a generic manufacturer may file an Abbreviated New Drug Application ("ANDA"). DPP Compl. ¶ 96. While an ANDA must show that the generic drug is therapeutically equivalent to the brand drug, it can rely on the scientific findings of safety and effectiveness included in the brand manufacturer's original NDA. *Id.* Generic drugs that are therapeutically equivalent to and are of the same dosage strength and form as their approved branded counterpart are assigned an "AB" rating by the FDA. *Id.*

For the FDA to approve an ANDA, a generic manufacturer must certify that the generic drug will not infringe any patents listed in the Orange Book. *Id.* ¶ 100. One of the four possible certifications is "that the patent for the brand drug is invalid or will not be infringed by the generic manufacturer's proposed product" (a "Paragraph IV certification"). *Id.*; 21 U.S.C. § 355(j)(2)(A)(vii). If a generic manufacturer files a Paragraph IV certification, it must notify the brand manufacturer, and the brand manufacturer can delay FDA approval of the ANDA by suing the generic manufacturer for patent infringement. DPP Compl. ¶ 101. If the brand manufacturer sues for patent infringement within forty-five days of receiving notice of the Paragraph IV certification, the FDA will not grant final approval of the ANDA until the earlier of (a) thirty months after the receipt of the Paragraph IV notice; or (b) a court decision that the patent is invalid or not infringed by the generic manufacturer's ANDA. 21 U.S.C.

§ 355(j)(5)(B)(iii); DPP Compl. ¶ 101. Thus, simply by filing suit, the brand manufacturer can forestall entry of the competitor drug for a period of time not to exceed thirty months.

To incentivize the manufacturing of generics, the Hatch-Waxman Amendments grants a 180-day exclusivity period to the first generic manufacturer that files a substantially complete ANDA with a Paragraph IV certification. DPP Compl. ¶ 103; 21 U.S.C. § 355(j)(5)(B)(iv), (D). During this exclusivity period, the FDA may not grant final approval to any other generic manufacturer's ANDA for the same brand drug. *Id.* Where multiple generic companies are the first to file substantially complete ANDAs with Paragraph IV certifications, they may be eligible to share the 180-day exclusivity period. *Id.* ¶ 106; 21 U.S.C. § 355(j)(5)(B)(iv).

III. Implications of Competition from Generics and a Brand Manufacturer's Incentives to Delay Generic Entry

On average, generic versions of brand drugs are 50% to 80% less expensive than brand drugs when there are multiple generic competitors on the market for a given brand drug. DPP Compl. ¶ 107. Every state has adopted laws that either require or permit pharmacies to automatically substitute less-expensive AB-rated generic equivalents for brand prescriptions (unless the prescribing physician has affirmatively requested the brand). *Id.* ¶ 108. Once a generic equivalent enters the market, the generic quickly captures sales of the brand drug, often capturing 80% or more of the brand's sales within the first six months. *Id.* Once multiple generic competitors enter, the competitive process accelerates, and multiple generic sellers typically compete vigorously with one another for sales by driving prices down. *Id.* ¶ 109.

Generic competition enables purchasers of the drug to purchase substantially cheaper generics instead of the more expensive brand drug and to benefit from when the brand company lowers prices to compete with generics. *Id.* ¶ 110. Accordingly, when generic entry is delayed, purchasers are harmed by having to pay more than they otherwise would have to pay. *Id.* ¶ 111.

Competition from generic drugs is viewed by brand-drug companies as a grave financial threat. *Id.* ¶ 109. When exclusivity is lost and generic entry occurs, the brand manufacturer can expect a significant drop in profits. *Id.* ¶ 112. Brand manufacturers thus have financial incentives to delay generic entry. *Id.* ¶ 113. One way to delay generic entry is through the regulatory waiting period initiated in response to patent litigation, as discussed above. *Id.* Brand manufacturers thus frequently take aggressive positions in listing patents in the Orange Book and then bring patent lawsuits against any generic competitor that files an ANDA with a Paragraph IV certification. *Id.* These patent lawsuits are often litigated to delay generic entry rather than to enforce valid patents against infringing products. *Id.* If the brand manufacturer can keep the litigation going long enough, it can obtain for itself a thirty-month delay in the entry of the generic competitor.

Brand manufacturers also can forestall competition from a generic manufacturer of a generic product by entering into settlements to resolve the lawsuits in which the generic competitor drops its patent challenge and agrees to delay entry in exchange for a payment from the brand manufacturer. *Id.* ¶ 114. These settlements are sometimes called "pay-for-delay" or "reverse-payment agreements." *Id.* As regulatory and other scrutiny of such agreements has increased, brand manufacturers and generic competitors have allegedly entered into increasingly elaborate agreements in an attempt to mask the fundamentally anticompetitive character of their agreements. *Id.* ¶ 115.

IV. Forest's NDA for Bystolic and Generic Defendants' ANDAs for Generic Versions of Bystolic

As part of the NDA for Bystolic, Forest listed two patents for inclusion in the FDA's Orange Book: U.S. Patent No. 6,545,040 ("the '040 Patent") and U.S. Patent No. 5,759,580 ("the '580 Patent"). *Id.* ¶¶ 4, 124. The '040 Patent issued on April 8, 2003 and expired on December

17, 2021. *Id.* ¶ 125. The '580 Patent issued on June 2, 1998 and expired on June 2, 2015. *Id.* ¶ 124.

Bystolic qualified for a five-year marketing exclusivity period during which no ANDAs may be filed. *Id.* ¶ 101. This period is reduced to four years if, at the end of four years, an ANDA is filed with a Paragraph IV certification. 21 U.S.C. § 355(j)(5)(F)(ii); DPP Compl. ¶ 101. If the manufacturer of a branded drug sues within forty-five days of receiving the Paragraph IV certification, the approval waiting period is extended to the earlier of (a) 7.5 years after the original NDA's approval; or (b) a court decision that the patent is invalid or not infringed by the generic manufacturer's ANDA. DPP Compl. ¶ 101. In the interim, the FDA may only grant tentative approval and not final approval of the ANDA. *Id.*

In December 2011, the seven Generic Defendants filed ANDAs with the FDA containing Paragraph IV certifications regarding the Bystolic patents. *Id.* ¶¶ 4, 140. They were the first generic manufacturers to file substantially complete ANDAs with Paragraph IV certifications. *Id.* As such, Generic Defendants were eligible to potentially share the 180-day exclusivity period during which the FDA would not grant final approval to any other generic manufacturer's ANDA for generic Bystolic. *Id.* ¶ 141. In February 2012, Generic Defendants notified Forest of their Paragraph IV certifications. *Id.* ¶ 142. Forest then had forty-five days to sue for patent infringement.

V. Bystolic Patent Litigation and the Settlement Agreements and Side Agreements between Forest and Generic Defendants

On March 13, 2012, in response to the Paragraph IV certification notices, Forest filed a patent infringement lawsuit in the U.S. District Court for the District of Delaware against Generic Defendants Torrent, Watson, Amerigen, Glenmark, and Hetero. *Id.* ¶ 144; *see also Forest Laboratories, Inc. v. Torrent Pharms. Ltd. et al*, 12-cv-305 (D. Del. Mar. 13, 2012).

Though some of the notices related to both the '040 and the '580 Patents, Forest only asserted the '040 Patent and declined to sue on the '580 Patent. DPP Compl. ¶¶ 124, 144.

The next day, on March 14, 2012, Forest filed a patent infringement lawsuit in the U.S. District Court for the Northern District of Illinois against Generic Defendants Indchemie and Alkem. *Id.* ¶ 145; *see also Forest Laboratories, Inc. v. Indchemie Health Specialties PVT. LTD. et al*, 12-cv-1855 (N.D. Ill. Mar. 14, 2012). Again, Forest only asserted the '040 Patent and declined to sue on the '580 Patent. DPP Compl. ¶ 145.

Pursuant to 28 U.S.C. § 1407, the District of Delaware action was transferred to the Northern District of Illinois, and the two patent cases were consolidated into one action (the "Nebivolol Patent Litigation"). *See In re Nebivolol Patent ('040) Litig.*, 12-cv-5026 (N.D. Ill. June 12, 2012). These lawsuits automatically triggered stays so that the FDA could not grant final approval of Generic Defendants' ANDAs before June 18, 2015, absent an earlier favorable decision in the suits for Generic Defendants. DPP Compl. ¶ 4.

From October 2012 through November 2013, Forest entered into settlements and side deals with the seven Generic Defendants to resolve the Nebivolol Patent Litigation. *Id.* ¶¶ 3, 151. In their settlement agreements with Forest, each Generic Defendant agreed not to sell generic Bystolic until September 17, 2021, three months before the expiration of the '040 Patent, unless another Generic Defendant entered the market earlier. *Id.* ¶ 3. Each settlement agreement allegedly also had a side deal. *Id.* ¶ 8.

The DPP Complaint alleges that, in connection with a merger between Forest and Actavis in 2014, Forest's outside counsel sought to review "all of the Bystolic settlement and licensing agreements as well as the side agreements with those generic companies." *Id.* Forest's in-house counsel responded to outside counsel that Forest had entered into settlement agreements with

Generic Defendants and that "[a]ll had side deals (one side was struck with Alkem, which is a related company with Indchemie)." *Id.* ¶¶ 8, 151. The merger agreement disclosed Forest's "material contracts," which were defined to include:

> any Contract involving the settlement of any action or threatened action (or series of related actions) (A) which will (x) involve payments after the date hereof of consideration in excess of $15,000,000 or (y) impose monitoring or reporting obligations to any other Person outside the ordinary course of business or (B) with respect to which material conditions precedent to the settlement have not been satisfied.

Id. ¶ 9. Forest listed the following agreements as material contracts in connection with the settlement of the Bystolic patent dispute:

- Hetero: "SETTLEMENT AGREEMENT between Forest Laboratories, Inc. and Forest Laboratories Holdings, Ltd., and Hetero USA Inc. and Hetero Labs Ltd. dated October 24, 2012 . . . together with the FINAL TERM SHEET between Hetero Drugs Ltd. and Forest Laboratories Ireland Ltd. dated October 5, 2012, in connection with the settlement of BYSTOLIC patent dispute." *Id.* ¶ 12.

- Torrent: "SETTLEMENT AGREEMENT between Forest Laboratories, Inc. and Forest Laboratories Holdings, Ltd., and Torrent Pharmaceuticals Ltd. and Torrent Pharma Inc. dated November 21, 2012 . . . together with the PATENT ASSIGNMENT AGREEMENT between Torrent Pharmaceuticals Ltd. and Forest Laboratories Holdings Ltd. dated November 21, 2012, in connection with the settlement of BYSTOLIC patent dispute." *Id.* ¶ 13.

- Alkem/Indchemie: "SETTLEMENT AGREEMENT between Forest Laboratories, Inc. and Forest Laboratories Holdings, Ltd., and Alkem Laboratories Ltd. dated November 27, 2012 . . . together with the TERM SHEET between Alkem Laboratories Ltd., Indchemie Health Specialties Private Ltd., and Forest Laboratories Ireland Ltd. dated November 28, 2012 in connection with the settlement of BYSTOLIC patent dispute. AMENDMENT NO. 1 TO SETTLEMENT AGREEMENT was executed on January 9, 2013 . . . . SETTLEMENT AGREEMENT between Forest Laboratories, Inc. and Forest Laboratories Holdings, Ltd., and Indchemie Health Specialties Private Ltd. dated November 27, 2012 . . . together with the TERM SHEET between Alkem Laboratories Ltd., Indchemie Health Specialties Private Ltd., and Forest Laboratories Ireland Ltd. dated November 28, 2012, in connection with the settlement of BYSTOLIC patent dispute." *Id.* ¶ 14.

- Glenmark: "SETTLEMENT AGREEMENT between Forest Laboratories, Inc. and Forest Laboratories Holdings, Ltd., and Glenmark Generics Inc., USA and Glenmark Generics Ltd. dated December 21, 2012 . . . together with the COLLABORATION AND OPTION AGREEMENT between Glenmark Pharmaceuticals S.A. and Forest Laboratories Holdings Ltd. dated December 21, 2012, in connection with the settlement of BYSTOLIC patent dispute." *Id.* ¶ 15.

- Amerigen: "SETTLEMENT AGREEMENT between Forest Laboratories, Inc. and Forest Laboratories Holdings, Ltd., and Amerigen Pharmaceuticals, Inc. and Amerigen Pharmaceuticals, Ltd. dated July 18, 2013 . . . together with the BINDING TERM SHEET COLLABORATION AGREEMENT between Forest Laboratories, Inc. and Amerigen Pharmaceuticals, Ltd. dated July 18, 2013, in connection with the settlement of BYSTOLIC patent dispute." *Id.* ¶ 16.

- Watson: "SETTLEMENT AGREEMENT between Forest Laboratories, Inc. and Forest Laboratories Holdings, Ltd., and Watson Laboratories, Inc. (NV), Watson Laboratories, Inc. (DE), Watson Laboratories, Inc. (NY), Watson Laboratories, Inc. (CT), Watson Pharma, Inc., and Actavis, Inc. dated November 6, 2013 . . . together with (a) the LETTER from Forest Laboratories, Inc. to Moksha8, Inc. dated November 1, 2013 and (b) TERMINATION AND RELEASE AGREEMENT between Actavis, Inc. and Moksha8, Inc. dated November 4, 2013, in connection with the settlement of BYSTOLIC patent dispute." *Id.* ¶ 17.

All of the settlement agreements with Generic Defendants provided licenses permitting them to launch their respective generic versions of Bystolic as of the date that is the later of (a) three calendar months prior to expiration of the '040 Patent, (b) the date of final FDA approval of the Generic Defendant's ANDA, or (c) earlier in certain circumstances. *Id.* ¶ 21. The earlier circumstances refer to the agreements' respective "contingent launch provisions" or "acceleration clauses," which permit a Generic Defendant to enter the market at the same time as any of its competitors if a competitor can enter the market earlier for some reason. *Id.* Unless an exception applied, the agreements allowed Forest to maintain monopoly profits and not face generic competitors until at least September 17, 2021, three months before patent expiration. *Id.* ¶ 23. Each of these settlement agreements and side agreements is discussed in greater detail below.

In light of the settlements, Forest avoided certain litigation costs. *Id.* ¶ 170. The DPP Complaint alleges that, according to the American Intellectual Property Law Association's 2013 Report of the Economic Survey, the median cost of patent litigation at that time for cases with more than $25 million at stake was $5–6 million. *Id.* It also alleges that, since the two separately filed patent cases were consolidated for proceedings in the Nebivolol Patent Litigation, Forest likely would have expended substantially less, in total, than it would have expended had the two patent cases involved a series of different and distinct patents and issues, or if they had proceeded independently of one another. *Id.* As a result, the DPP Complaint alleges that Forest's saved litigation costs with respect to each Generic Defendant were far less than $5–6 million. *Id.*

It is alleged that but for the agreements settling the patent litigation, Generic Defendants would have launched their generic products earlier at one of three possible times: (a) "at risk," meaning when a generic has received final approval from the FDA to market its product but while the patent litigation is continuing; (b) upon prevailing against Forest in the underlying patent litigation; or (c) via lawful settlement agreements providing for earlier negotiated entry dates unaffected by any induced delay. *Id.* ¶ 26. Under these scenarios, Plaintiffs would have paid substantially less for nebivolol hydrochloride, and Defendants' conduct delayed the entry of less expensive nebivolol hydrochloride, fixed the price of nebivolol hydrochloride, and allocated the whole United States market for nebivolol hydrochloride to Forest until three months before patent expiration. *Id.* ¶¶ 27–28.

PROCEDURAL HISTORY

This case involves two sets of lawsuits based on substantially identical facts. The first actions in this case were filed in July 2020. The first set of lawsuits are brought by Direct Purchaser Plaintiffs and Retailer Plaintiffs who bring claims for damages under federal antitrust

law. The second set of lawsuits are brought by End-Payor Plaintiffs under state antitrust and consumer-protection laws and for injunctive relief under federal antitrust law. The Direct Purchaser Plaintiffs' actions were consolidated, the End-Payor Plaintiffs' actions were consolidated, and the two consolidated actions and the two Retailer Plaintiffs' actions were coordinated with one another under one docket to promote efficiency in managing and litigating the cases. Dkt. Nos. 50, 82, 86, 204; *CVS Action*, 20-cv-10087 (S.D.N.Y.), ECF No. 19; *Walgreen Action*, 20-cv-9793 (S.D.N.Y.), ECF No. 20. Though Defendants moved to transfer the cases to the District of New Jersey, Dkt. No. 79, the Court denied the motion to transfer venue, Dkt. No. 178. On December 3, 2020, Direct Purchaser Plaintiffs filed their Consolidated and Amended Class Action Complaint, Dkt. No. 111, and End-Payor Plaintiffs filed their Consolidated Class Action Complaint, Dkt. No. 113. On December 23, 2020, Retailer Plaintiffs filed their respective amended complaints. *CVS Action*, 20-cv-10087 (S.D.N.Y.), ECF No. 20; *Walgreen Action*, 20-cv-9793 (S.D.N.Y.), ECF No. 21. Thereafter, Nonresident Defendants moved to dismiss the End-Payor Plaintiffs' complaint for lack of personal jurisdiction, Dkt. No. 215; Teva Israel moved to dismiss all claims against it for lack of personal jurisdiction, Dkt. No. 218; Defendants moved to dismiss Direct Purchaser and Retailer Plaintiffs' complaints for failure to state a claim, Dkt. No. 223; and Defendants moved to dismiss End-Payor Plaintiffs' complaint for failure to state a claim, Dkt. No. 226. In response to Defendants' various motions to dismiss, all Plaintiffs elected to amend their complaints, Dkt. No. 240, and the Court denied the motions to dismiss without prejudice as moot, Dkt. No. 241.

On March 15, 2021, the operative amended complaints in this case were filed: the DPP Complaint, Dkt. No. 250; the Retailer Plaintiffs' Complaints, *CVS Action*, 20-cv-10087 (S.D.N.Y.), ECF No. 35; *Walgreen Action*, 20-cv-9793 (S.D.N.Y.), ECF No. 34; and the EPP

Complaint, Dkt. No. 251. The Direct Purchaser and Retailer Plaintiffs' Complaints bring claims for violations of Section 1 of the Sherman Act, 15 U.S.C. § 1, alleging agreements not to compete with brand and generic Bystolic between Forest and Generic Defendants, and claims for violations of Section 2 of the Sherman Act, 15 U.S.C. § 2, alleging conspiracy to monopolize as to brand and generic Bystolic through agreements between Forest and Generic Defendants and alleging monopolization and monopolistic scheme against Forest. DPP Compl. ¶¶ 203–345; *CVS Action*, 20-cv-10087 (S.D.N.Y.), ECF No. 35 ¶¶ 182–307; *Walgreen Action*, 20-cv-9793 (S.D.N.Y.), ECF No. 34 ¶¶ 184–309. The EPP Complaint brings claims for monopolization and monopolistic scheme under various state antitrust laws against Forest; for conspiracy to monopolize under various state antitrust laws against all Defendants; for combination and conspiracy in restraint of trade under various state antitrust laws against all Defendants; for unfair or deceptive trade practices under various state consumer-protection laws against all Defendants; and for declaratory and injunctive relief against all Defendants under Section 16 of the Clayton Act, 15 U.S.C. § 26, for all Defendants' violations of Sections 1 and 2 of the Sherman Act. EPP Compl. ¶¶ 290–457.

On April 23, 2021, Defendants moved to dismiss the Direct Purchaser and Retailer Plaintiffs' Complaints, Dkt. No. 267, and moved to dismiss End-Payor Plaintiffs' Complaint, Dkt. No. 271. That same day, Defendant Teva Israel moved pursuant to Federal Rule of Civil Procedure 12(b)(2) to dismiss the claims against it for lack of personal jurisdiction, Dkt. No. 260, and the Nonresident Defendants moved pursuant to Federal Rule of Civil Procedure 12(b)(2) to dismiss for lack of personal jurisdiction the EPP Complaint's ninety-nine non-New York, state-law claims, Dkt. No. 265. After the four motions to dismiss were fully briefed, the Court held oral argument on the motions on December 14, 2021.

DISCUSSION

I. Motion to Dismiss Direct Purchaser and Retailer Plaintiffs' Complaints

The Court turns first to Defendants' motion to dismiss the Direct Purchaser and Retailer Plaintiffs' Complaints for failure to state a claim. For brevity, in this section of the discussion, the Court's references to "Direct Purchaser Plaintiffs" and the "DPP Complaint" encompass Retailer Plaintiffs and Retailer Plaintiffs' Complaints, respectively.

Defendants argue that the settlement agreements and side agreements between Forest and each of the Generic Defendants are lawful, that the Direct Purchaser Plaintiffs' Complaint depends on improper generalized group pleading, that Direct Purchaser Plaintiffs' theories of causation fail as a matter of law and should be struck from the pleading, and that Direct Purchaser Plaintiffs' construction of the Sherman Act violates due process. Dkt. No. 269.

To survive a motion to dismiss pursuant to Federal Rule of Civil Procedure 12(b)(6) for failure to state a claim upon which relief can be granted, a complaint must include "sufficient factual matter, accepted as true, to 'state a claim to relief that is plausible on its face.'" *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (quoting *Bell Atlantic Corp. v. Twombly*, 550 U.S. 554, 570 (2007)). A complaint must offer more than "labels and conclusions," "a formulaic recitation of the elements of a cause of action," or "naked assertion[s]" devoid of "further factual enhancement" in order to survive dismissal. *Twombly*, 550 U.S. at 555, 557. The ultimate question is whether "[a] claim has facial plausibility, [i.e.,] the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Iqbal*, 556 U.S. at 678. "Determining whether a complaint states a plausible claim for relief will . . . be a context-specific task that requires the reviewing court to draw on its judicial experience and common sense." *Id.* at 679. Put another way, the plausibility requirement "calls for enough fact to raise a reasonable expectation that discovery will reveal

evidence [supporting the claim]." *Twombly*, 550 U.S. at 556; *see also Matrixx Initiatives, Inc. v. Siracusano*, 563 U.S. 27, 46 (2011).[8]

A. Large and Unjustified Reverse Payments Under *FTC v. Actavis*

The theory of Direct Purchaser Plaintiffs' case relies heavily on *FTC v. Actavis*, 570 U.S. 136 (2013). In *FTC v. Actavis*, the Supreme Court held that antitrust cases premised on reverse-payment settlements of patent litigation—"reverse" because the settlement requires the patentee to pay the alleged infringer rather than the other way around—can sometimes violate the antitrust laws and must be evaluated under the rule of reason. *Id.* at 140, 159. That case arose in a similar context as that alleged by Direct Purchaser Plaintiffs here.

In *FTC v. Actavis*, two generic drug manufacturers—Actavis, Inc. and Paddock Laboratories ("Paddock")—filed ANDAs for a generic drug modeled after the brand-name drug AndroGel, and the brand manufacturer Solvay Pharmaceuticals ("Solvay") initiated paragraph IV patent litigation against the two generic manufacturers pursuant to the Hatch-Waxman regulatory framework. *Id.* at 144–45. A fourth manufacturer, Par Pharmaceutical ("Par"), did not file its own application but joined forces with Paddock. *Id.* Solvay settled the patent litigation with the generic manufacturers in 2006. *Id.* at 145. Under the terms of the settlement, Actavis agreed not to bring its generic product to market until a date in 2015, nine years after the date of the settlement but sixty-five months before the brand manufacturer's patent expired. *Id.* Actavis also agreed to promote AndroGel to urologists. *Id.* The other generic manufacturers

[8] Defendants argue that Direct Purchaser Plaintiffs' allegations that the side agreements were pretextual sound in fraud and therefore must be pleaded with particularity in accordance with Federal Rule of Civil Procedure 9(b). Dkt. No. 269 at 16–17. The Court will not apply a heightened pleading standard. In *FTC v. Actavis*, when faced with similar allegations—that the "true point of the payments" from the brand manufacturer to the generics "was to compensate the generics for agreeing not to compete against [the brand-name drug] until 2015," 570 U.S. 136, 145 (2013)—the Supreme Court did not impose the heightened pleading standard of Rule 9(b).

made generally similar promises. *Id.* In exchange, the brand manufacturer agreed to pay millions of dollars to each generic manufacturer—$12 million in total to Paddock; $60 million in total to Par; and about $19 to $30 million annually for nine years to Actavis. *Id.*

The Federal Trade Commission ("FTC") sued the brand manufacturer and the three generic manufacturers for violating Section 5 of the Federal Trade Commission Act, 15 U.S.C. § 45. The FTC's theory was that the parties had engaged in a thinly camouflaged agreement to restrain trade: The generic manufacturers had agreed to refrain from launching their own generic products to compete with AndroGel for nine years in exchange for a share of the brand manufacturer's monopoly profits. *Actavis*, 570 U.S. at 145. The implicit premise was that, but for the agreement, the generic manufacturers would have been able to launch their competing products earlier. Although the pharmaceutical companies argued that the payments compensated the generics for services promised to be performed, the FTC claimed that the payments compensated the generics for agreeing not to compete against AndroGel until 2015. *Id.* The district court dismissed the FTC's complaint for failing to set forth an antitrust law violation, and the Court of Appeals for the Eleventh Circuit affirmed. *Id*. at 145–46.

The Supreme Court reversed and held that the FTC's dismissed complaint alleged reverse-payment settlements that may violate the antitrust laws and that the FTC's lawsuit should have been allowed to proceed. *Id.* at 141. The *Actavis* Court noted that "[t]he FTC alleges that in substance, the plaintiff agreed to pay the defendants many millions of dollars to stay out of its market, even though the defendants did not have any claim that the plaintiff was liable to them for damages." *Id.* at 147. And the Supreme Court continued that "[t]hat form of settlement is unusual" and that "there is reason for concern that settlements taking this form tend to have significant adverse effects on competition." *Id.* at 147–48.

The *Actavis* Court based its conclusion on five sets of considerations. *Id.* at 153. First, reverse-payment settlements of patent litigation have "the potential for genuine adverse effects on competition." *Id.* (internal quotation marks omitted). A "payment in return for staying out of the market . . . simply keeps prices at patentee-set levels, potentially producing the full patent-related $500 million monopoly return while dividing that return between the challenged patentee and the patent challenger"—"[t]he patentee and the challenger gain; the consumer loses." *Id.* at 154. Where there are indications that the brand manufacturer pays a generic manufacturer a sum even larger than what the generic would gain in profits if it won the paragraph IV litigation and entered the market, "a payment of this size cannot in every case be supported by traditional settlement considerations." *Id.* "The payment may instead provide strong evidence that the patentee seeks to induce the generic challenger to abandon its claim with a share of its monopoly profits that would otherwise be lost in a competitive market." *Id.*

Second, the Supreme Court recognized that "these anticompetitive consequences will at least sometimes prove unjustified." *Id.* at 156. "[O]ffsetting or redeeming virtues are sometimes present." *Id.* The *Actavis* Court explained:

> The reverse payment, for example, may amount to no more than a rough approximation of the litigation expenses saved through the settlement. That payment may reflect compensation for other services that the generic has promised to perform—such as distributing the patented item or helping to develop a market for that item. There may be other justifications. Where a reverse payment reflects traditional settlement considerations, such as avoided litigation costs or fair value for services, there is not the same concern that a patentee is using its monopoly profits to avoid the risk of patent invalidation or a finding of noninfringement. In such cases, the parties may have provided for a reverse payment without having sought or brought about the anticompetitive consequences we mentioned above.

Id. Yet, the Supreme Court continued, the possibility that a reverse payment may in some circumstances be supported by legitimate reasons "does not justify dismissing the FTC's complaint." *Id.* Rather "[a]n antitrust defendant may show in the antitrust proceeding that

legitimate justifications are present, thereby explaining the presence of the challenged term and showing the lawfulness of that term under the rule of reason." *Id.*

Third, the Supreme Court reasoned that "where a reverse payment threatens to work unjustified anticompetitive harm, the patentee likely possesses the power to bring that harm about in practice." *Id.* at 157. And "[a]t least, the size of the payment from a branded drug manufacturer to a prospective generic is itself a strong indicator of power—namely, the power to charge prices higher than the competitive level." *Id.*

Fourth, the *Actavis* Court set forth the reasons for why such an antitrust action would not be administratively infeasible. *Id.* "[I]t is normally not necessary to litigate patent validity to answer the antitrust question (unless, perhaps, to determine whether the patent litigation is a sham)." *Id.* (citation omitted). Rather:

> An unexplained large reverse payment itself would normally suggest that the patentee has serious doubts about the patent's survival. And that fact, in turn, suggests that the payment's objective is to maintain supracompetitive prices to be shared among the patentee and the challenger rather than face what might have been a competitive market—the very anticompetitive consequence that underlies the claim of antitrust unlawfulness.

Id. In short, "the size of the unexplained reverse payment can provide a workable surrogate for a patent's weakness, all without forcing a court to conduct a detailed exploration of the validity of the patent itself." *Id.* at 158.

The fifth and final consideration was that "the fact that a large, unjustified reverse payment risks antitrust liability does not prevent litigating parties from settling their lawsuit" in other ways. *Id.* For example, the brand manufacturer may "allow[] the generic manufacturer to enter the patentee's market prior to the patent's expiration, without the patentee paying the challenger to stay out prior to that point." *Id.* When a settlement includes a reverse payment, the relevant antitrust question is why. "If the basic reason is a desire to maintain and to share patent-

generated monopoly profits, then, in the absence of some other justification, the antitrust laws are likely to forbid the arrangement." *Id.*

The *Actavis* Court thus summarized its discussion:

> [A] reverse payment, where large and unjustified, can bring with it the risk of significant anticompetitive effects; one who makes such a payment may be unable to explain and to justify it; such a firm or individual may well possess market power derived from the patent; a court, by examining the size of the payment, may well be able to assess its likely anticompetitive effects along with its potential justifications without litigating the validity of the patent; and parties may well find ways to settle patent disputes without the use of reverse payments.

Id. These considerations led the *Actavis* Court to conclude that such settlements should not be categorically shielded from antitrust scrutiny. *Id.*

At the same time, however, the Supreme Court also rejected the FTC's argument that reverse-payment settlements should be deemed "presumptively unlawful" and be reviewed "via a 'quick look' approach." *Id.* at 158–59. Under that approach, any agreement pursuant to which a generic manufacturer agreed to honor a patent and to refrain from entering the market prior to the patent's expiration would be presumptively unlawful if the generic received payment in exchange for that promise, and the burden would then shift to the parties to that agreement to provide a legitimate pro-competitive justification for it. A complaint based solely on those allegations would survive a motion to dismiss, and the defendants would have to prove that "any money that changed hands was for something other than a delay, such as the generic manufacturer's provision of property or services unrelated to the brand-name manufacturer's monopoly." Brief for the Petitioner at 37, *FTC v. Actavis*, 570 U.S. 136 (2013) (No. 12-416) (internal quotation marks and citation omitted). The Supreme Court rejected the FTC's argument. *Actavis*, 570 U.S. at 158–59. It held that a quick-look approach "is appropriate only where an observer with even a rudimentary understanding of economics could conclude that the arrangements in question would have an anticompetitive effect on customers and markets." *Id.*

at 159 (internal quotation marks omitted). The reverse-payment agreement did not fit into that category; it was not presumptively wrongful. *Id.* The Supreme Court reasoned that the anticompetitive nature of the agreement would depend on more particularized facts because "the likelihood of a reverse payment bringing about anticompetitive effects depends upon its size, its scale in relation to the payor's anticipated future litigation costs, its independence from other services for which it might represent payment, and the lack of any other convincing justification." *Id.* "These complexities," including also the variance among industries in the "existence and degree of any anticompetitive consequence," justified application of the rule of reason. *Id.*

Since *Actavis*, the lower federal courts have struggled with the standards set forth by the Supreme Court.[9] *See, e.g.*, *In re Namenda Indirect Purchaser Antitrust Litig.*, 2021 WL 2403727, at *11 (S.D.N.Y. June 11, 2021) (describing the Supreme Court's *Actavis* decision as "an opinion that has long bedeviled district courts"); *In re Aggrenox Antitrust Litig.*, 94 F. Supp. 3d 224, 242 (D. Conn. 2015) ("District courts applying *Actavis* have . . . had relatively little guidance on the question of what constitutes a 'large' and 'unjustified' reverse payment . . . ."); *In re Lipitor Antitrust Litig.*, 868 F.3d 231, 254 (3d Cir. 2017) ("For its part, the Supreme Court in *Actavis* was deliberately opaque about the parameters of reverse payment antitrust claims.").

[9] The challenge is compounded by some ambiguity within *Actavis* itself. In summarizing its holding, the Supreme Court stated, "a reverse payment, where large and unjustified, can bring with it the risk of significant anticompetitive effects," and also stated, "one who makes *such* a payment may be unable to explain and justify it." *Id.* at 158. The *Actavis* Court elsewhere stated that where the plaintiff has alleged a large and unjustified payment, "[a]n antitrust defendant may show in the antitrust proceeding that legitimate justifications are present, thereby explaining the presence of the challenged term and showing the lawfulness of that term under the rule of reason." *Id.* at 156. It is not clear from the four corners of the opinion the circumstances where a reverse payment may be both large and unjustified and still able to be explained and justified by the defendant.

The Second Circuit has not yet addressed what is sufficient to plead a large and unjustified reverse payment to overcome a motion to dismiss. The courts that have considered reverse-payment agreements have stated that, "[t]o trigger antitrust concern under *Actavis*, a settlement term must be '(1) a "payment" that is (2) made in "reverse"—that is, from the patent holder to the alleged infringer—and is [(3)] "large," and (4) "unexplained."'" *Sergeants Benevolent Ass'n Health & Welfare Fund v. Acta Vis, PLC*, 2016 WL 4992690, at *13 (S.D.N.Y. Sept. 13, 2016) (quoting *In re Actos End Payor Antitrust Litig.*, 2015 WL 5610752, at *11 (S.D.N.Y. Sept. 22, 2015)). "Because the existence and degree of any anticompetitive effects may vary depending on the particular settlement and the relevant industry, plaintiffs must show that the settlements are anticompetitive under the rule of reason analysis applied to other types of antitrust claims." *Id.* (internal quotation marks omitted). Moreover,

> [i]n this Circuit, [the rule of reason analysis] involves three steps: First, the plaintiff bears the initial burden of showing that the defendant's conduct had an actual adverse effect on competition as a whole in the relevant market. If plaintiff satisfies this burden, the burden then shifts to the defendant to offer evidence that its conduct had pro-competitive effects. If the defendant is able to offer such proof, the burden shifts back to plaintiff, who must prove that any legitimate competitive effects could have been achieved through less restrictive alternatives.

Id. (alterations adopted) (citing *Arkansas Carpenters Health & Welfare Fund v. Bayer AG*, 604 F.3d 98, 104 (2d Cir. 2010)).

However, those general statements beg the question what makes a payment "large" or "unjustified" and what facts must be alleged to plead a claim and open the doors to discovery. "In *Actavis*, the Court did not say what constitutes a 'large' or 'unjustified' reverse payment, but it instead instructed courts (1) to compare a payment to the payor's future litigation costs as a measure of scale to determine if it was 'large,' and (2) to consider whether a payment 'reflects traditional settlement considerations, such as avoided litigation costs or fair value for services' to determine if it was justified." *Id.* at *14.

Courts in this Circuit have taken somewhat different approaches to those questions. For example, in *In re Actos End Payor Antitrust Litigation*, Judge Abrams concluded that "to meet their pleading burden as to whether the payments were 'large' and 'unjustified,' Plaintiffs must plausibly allege a factual basis for the Court to reasonably estimate the value of the settlement terms." 2015 WL 5610752, at *19. Judge Abrams continued, "Although Plaintiffs need not provide precise calculations at the pleading stage, here, they do not even attempt to provide a factual basis for the 'tens' and 'hundreds of millions' of dollars allegedly paid by [the brand manufacturer]." *Id.* Accordingly, those "bare allegations" were "insufficient for the Court to make a reasonable estimate of the settlements' value and determine whether they constituted large and unjustified payments." *Id.; see also In re Opana ER Antitrust Litig.*, 2016 WL 738596, at *8–9 (N.D. Ill. Feb. 25, 2016) ("[I]n order to raise a right to relief above the speculative level, [plaintiffs] must provide some reliable foundation to show an estimated value of the reverse payment and how that estimate was calculated. Further, [plaintiffs'] allegation that the reverse payment was 'an amount far above any litigation costs saved by Endo (or Impax) by settling,' fails to calculate what those saved costs actually were. Without this information, it is impossible to determine whether the payment was 'large' or 'unjustified' in comparison to the avoided litigation costs and any other services provided from Impact to Endo." (citation omitted)).

In *In re Aggrenox Antitrust Litigation*, Judge Underhill acknowledged that, "among the stronger of the defendants' arguments" is the argument that "the plaintiffs have not attempted to assign dollar values with significant precision or very obvious methodological justification to the various provisions of the settlement." 94 F. Supp. 3d at 244. But he ultimately concluded that such allegations were not necessary because "very precise and particularized estimates of fair value and anticipated litigation costs may require evidence in the exclusive possession of the

defendants, as well as expert analysis, and . . . these issues are sufficiently factual to require discovery." *Id.* Judge Underhill could not "conclude simply from the absence of precise figure that the pleadings represent formulaic recitations of elements and allegations that fail to rise above the speculative." *Id.* at 244–45. Rather, the complaints made "specific allegations about the terms of the settlement and their relative value that are plausible on their face." *Id.* at 245. The plaintiffs had "alleged that the total payment [was] far greater than the fair value of the services falling under [a] Co-Promotion Agreement, and therefore constitute[d] a large and unjustifiable reverse payment, which they allege[d was] especially clear since payment [was] guaranteed even without the generation of additional sales." *Id.* at 243. They also "allege[d] that [the brand manufacturer] agreed not to launch its own 'authorized generic' during [the generic manufacturer's] 180-day exclusivity period under the Hatch-Waxman Act, which further enlarged the reverse payment by constituting an additional unexplained transfer of value to [the generic]." *Id.* at 244. "Whether the plaintiffs can substantiate those allegations may be an issue for summary judgment or trial, but for purposes of the motions to dismiss, [the court] must accept the allegations as true and draw all reasonable inferences in the plaintiffs' favor." *Id.* at 245.

Similarly, in *Sergeants Benevolent Association Health and Welfare Fund v. Acta Vis, PLC*, Judge McMahon determined that the questions of whether a reverse payment is large and unjustified represent "intrinsically fact-based determinations [that] cannot be made on a pre-answer motion to dismiss." 2016 WL 4992690, at *14. There, the plaintiffs had alleged that, contemporaneously with the execution of each of the settlement agreements, the brand manufacturer made payments to cover the generic manufacturers' litigation costs and to provide other compensation for promoting the brand drug and also granted early-entry licenses, which

allowed the generics to manufacture a generic version of the drug three months before patent expiration. *Id.* at *13–14. Judge McMahon concluded that "[d]iscovery [was] needed to reveal whether the payments Forest made to the Generic Defendants were actually commensurate with the legal fees they expected to pay over the course of the ANDA A patent litigation, or constituted reasonable compensation for promoting brand-name Namenda IR to doctors and patients." *Id.* at *14. The "[p]laintiffs [had] alleged that these payments exceeded reasonable costs and compensation." *Id.* And "without evidence related to what the Generic Defendants had already paid in legal fees and what they reasonably could be expected to continue paying if they had continued to litigate the patent infringement actions, the Court cannot say, as a matter of law, that the payments were not large and unjustified." *Id.* It appears that under Judge McMahon's approach, as well as under Judge Underhill's approach, a plaintiff need only plead the approximate amount of a payment and that it is large and unjustified in order to state a claim for relief under the general pleading standards of Rule 8 of the Federal Rules of Civil Procedure.

The Third Circuit has taken a similar approach. It has held that "[a] plaintiff can meet this pleading standard without describing in perfect detail the world without the reverse payment, calculating reliably the payment's exact size, or preempting every possible explanation for it." *Fed. Trade Comm'n v. AbbVie Inc*, 976 F.3d 327, 356 (3d Cir. 2020); *see also In re Lipitor Antitrust Litig.*, 868 F.3d at 254. "If a plaintiff plausibly alleges that an agreement's anticompetitive effects outweigh its procompetitive virtues, the district court must accept that allegation and allow the plaintiff to take discovery. If genuine issues of material fact remain, the rule-of-reason analysis is for the factfinder, not the court." *Fed. Trade Comm'n v. AbbVie Inc*, 976 F.3d at 356.

In describing the level of detail required to be pleaded for a reverse payment to be considered "large," the Third Circuit recounted the allegations in *Actavis* on the size of the reverse payment:

> There, the FTC alleged simply that a patentee "agreed to pay [a generic manufacturer] $10 million per year for six years," "agreed to pay [another generic manufacturer] $2 million per year for six years," and "projected that it would pay [a third generic manufacturer] about $19 million during the first year of its agreement, rising to over $30 million annually by the end of the deal."

In re Lipitor Antitrust Litig., 868 F.3d at 254–55 (alterations in original) (citations omitted). Further, "the FTC's complaint did not preemptively negate justifications for the reverse payments" and instead "simply alleged that the payments were meant to, and did, induce delay of likely successful patent challenges through the sharing of monopoly profits." *Id.* at 255. In other words, "[t]o plausibly allege an unjustified reverse payment, an antitrust plaintiff need only allege the absence of a convincing justification for the payment." *Id.* at 256 (internal quotation marks omitted). Allegations that the value of the released patent litigation claims far exceeds any litigation costs the brand manufacturer avoided by settling are sufficient. *Id.* "[A]ll that need be alleged, at this juncture [i.e., the motion-to-dismiss stage], is that those [saved litigation] costs fail to explain the hundreds of millions of dollars of liability released by [the brand manufacturer]." *Id.* "[F]inely calibrated litigation cost estimates . . . are unnecessary at this stage of the litigation." *Id.*

In determining what must be pleaded to survive a motion to dismiss, the Court in the instant case takes additional guidance both from the Supreme Court's decision in *Twombly* and from the *Actavis* Court's rejection of the FTC's quick-look approach to reverse-payment settlements. The approach taken by those courts that have permitted complaints to go forward only on general allegations that a reverse payment is large and unjustified seems to be animated by a concern that applying the pleading standards too rigidly would permit many anticompetitive

agreements to go unprosecuted and could render *Actavis* and the Sherman Act's protection against pay-for-delay agreements an empty promise: Clever competitors would shield their agreement from any review by characterizing those payments that are for delay as for consideration for some other service. Although some such characterizations might be accurate, a consumer who lacks information about the value of the service or the motivation for entering the agreement would have no means to challenge the competitors' characterization, obtain discovery, and ask a court to decide whether it was pretextual.

The Supreme Court addressed in *Twombly* the generalized concern that a requirement that a plaintiff plead facts to support a claim might result in some, and perhaps much, anticompetitive conduct going unredressed. The question there was whether allegations of parallel conduct along with the claim that the defendants entered into an agreement to restrain competition and to prevent competitive entry into each other's respective markets was sufficient to state a claim for relief and to require an answer and at least some minimal discovery. Justice Stevens' dissent reasoned that the alleged conduct was "entirely consistent with the *presence* of the illegal agreement alleged in the complaint," that plaintiffs were entitled to an answer at least "denying a charge that [defendants] in fact engaged in collective decisionmaking," and that any concerns that "[p]rivate antitrust litigation can be enormously expensive" can be addressed by "careful case management, including strict control of discovery." *Twombly*, 550 U.S. at 573–74 (Stevens, J., dissenting). The Supreme Court majority answered that conduct that is consistent with and equally explicable by a pro-competitive justification—by each defendant acting in its own independent interest—and that raises only the possibility of anticompetitive conduct is not sufficient to state a claim and to subject the defendants to what it characterized as the "potentially enormous expense of discovery." *Id.* at 559; *see also id.* at 556. The *Twombly*

Court was not oblivious to the fact that "in antitrust cases, . . . the proof is largely in the hands of the alleged conspirators," *id.* at 586 (Stevens, J., dissenting) (internal quotation marks omitted) (quoting *Hospital Building Corp. v. Trustees of Rex Hospital*, 425 U.S. 738, 746 (1976)), and that its decision would allow certain anticompetitive conduct to go unpunished. It was just skeptical that careful case management could weed out unmeritorious claims; and the majority concluded that the cost to defendants and to the judicial system of "allowing a potentially massive factual controversy to proceed" outweighed the risk that some meritorious claims might be dismissed. *Id.* at 558 (quoting *Associated Gen. Contractors of Cal., Inc. v. Carpenters*, 459 U.S. 519, 528 n.17 (1983)).

The same concern—that wily defendants not be permitted to escape review and should be required to at least answer—also appears to have motivated the FTC's "quick-look" argument in *Actavis*. In its argument before the Supreme Court, the FTC recognized that a reverse-payment agreement was not necessarily anticompetitive and could be consistent with pro-competitive conduct. The FTC stated that an agreement might not be anticompetitive if "the payment was commensurate with the litigation costs that the brand-name manufacturer avoided by settling." Brief for the Petitioner at 38, *FTC v. Actavis*, 570 U.S. 136 (2013) (No. 12-416). According to the FTC, it also might not be anticompetitive if "the parties could show that any money that changed hands was for something other than a delay, such as the generic manufacturer's provision of property or services unrelated to the brand-name manufacturer's monopoly." *Id.* at 37 (internal quotation marks and citation omitted). "Although there is no fixed formula for making that showing, and a court would need to consider the totality of the circumstances surrounding the agreement," *id.*, the FTC provided a list of relevant considerations for a court to consider, including:

> whether the payment reflected bona fide fair consideration for the property or services; whether other terms of the side transaction comported with industry standards; the existence of previous dealings between the parties on the subject matter of the side transaction; a history of demonstrated interest in or need for the property or services on the part of the brand-name manufacturer; and the course and content of the manufacturers' negotiations over the agreements.

Id. at 37–38. The FTC simply argued that it should be up to the defendants to prove those facts and that, if the plaintiff proved the existence of an agreement pursuant to which the generic manufacturer agreed not to enter the market before a patent expired and the brand manufacturer agreed to pay the generic money or consideration, the agreement should be presumed to be anticompetitive, thus shifting the burden to the defendants in a rule-of-reason analysis to offer a procompetitive justification. *Id.* at 33, 37.

The Supreme Court, however, rejected the FTC's proposed quick-look approach to such agreements, *see* 570 U.S. at 159, and held instead that it is insufficient for a plaintiff to merely establish the existence of a reverse-payment agreement to shift the burden to the defendants to offer procompetitive reasons to justify it. The Supreme Court thus held that it was not up to the defendants to show evidence in the first instance that the agreement was consistent with pro-competitive conduct. Rather, it appears that the *Actavis* Court concluded that the plaintiffs must show the absence of one or more of the factors that would be consistent with a pro-competitive justification. If, for example, a payment from a brand manufacturer to a generic manufacturer would be pro-competitive (even if the generic manufacturer also agreed to honor a patent) because it was consistent with "previous dealings between the parties on the subject matter of the side transaction" or "a history of demonstrated interest in or need for the property or services on the part of the brand-name manufacturer," it would fall to the plaintiff in the first instance to allege facts suggesting the absence of any such pro-competitive justification. In the words of the *Twombly* Court, conduct that is equally consistent with a pro-competitive as with an

anticompetitive justification is not sufficient to "nudge[] [plaintiffs'] claims across the line from conceivable to plausible." 550 U.S. at 570.

"[T]o determine what the plaintiff must plausibly allege at the outset of a lawsuit, [the court] usually ask[s] what the plaintiff must prove in the trial at its end." *Comcast Corp. v. Nat'l Ass'n of Afr. Am.-Owned Media*, 140 S. Ct. 1009, 1014 (2020). It thus appears, and the Court holds, that to state a claim under *Actavis*, a plaintiff must allege more than a general statement simply asserting that a reverse payment is large and unjustified (or was made pursuant to a simultaneously executed side agreement) and that the generic manufacturer agreed not to enter the market before the patent expired. Such a standard would replicate at the pleading stage the "quick-look" approach the Supreme Court rejected at least for the trial stage. Rather, the plaintiff must plead *facts* that would support the claim that the reverse payment was "large" and "unjustified," i.e., that it was not simply possible that the defendants engaged in the anticompetitive conduct of paying the generic manufacturer to forego entering the market but that it was plausible.

A showing that a reverse payment is "large" can be established by factual allegations plausibly suggesting that the payment is larger than the payor's anticipated future litigation costs. *See Actavis*, 570 U.S. at 159 (describing likelihood of reverse payment bringing about anticompetitive effects as dependent on payment's "scale in relation to the payor's anticipated future litigation costs"); *Sergeants Benevolent Ass'n*, 2016 WL 4992690, at *14; *In re Opana ER Antitrust Litig.*, 162 F. Supp. 3d at 718; *cf. In re Aggrenox Antitrust Litig.*, 94 F. Supp. 3d at 243 ("[P]ayments smaller than avoided litigation costs are presumptively not large and unexplained under *Actavis*, and represent a *de facto* safe harbor . . . ."). *Actavis* specifically directs courts to consider the reverse payment's scale in comparison to the payor's anticipated future litigation

costs—not relative to other figures such as the possible profits a generic manufacturer could make by entering the market for the brand-name drug or the brand manufacturer's profits on that drug. *See In re Solodyn (Minocycline Hydrochloride) Antitrust Litig.*, 2015 WL 5458570, at *9 (D. Mass. Sept. 16, 2015) ("*Actavis* specifically provided that an appropriate benchmark for the size of a reverse payment is 'its scale in relation to the payor's anticipated future litigation costs.'" (alteration adopted)). It is also not necessary that the plaintiff allege "very precise and particularized" estimates of actual anticipated litigation costs; such facts likely are in the exclusive possession of defendants and may require expert analysis. *In re Aggrenox Antiturst Litig.*, 94 F. Supp. 3d at 244–45.

In addition, a plaintiff must allege facts to plausibly suggest that the reverse payment is "unjustified." An unjustified reverse payment is one that does not reflect traditional settlement considerations such as avoided litigation costs or fair value for services. *See Sergeants Benevolent Ass'n*, 2016 WL 4992690, at *14; *In re Opana ER Antitrust Litig.*, 162 F. Supp. 3d at 718. The FTC in *Actavis* mentioned both of these considerations in explaining what might justify a reverse payment. *See* Brief for the Petitioner at 37–38, *FTC v. Actavis*, 570 U.S. 136 (2013) (No. 12-416) (discussing payments that "reflect[] bona fide fair consideration for the property or services" or are "commensurate with the litigation costs that the brand-name manufacturer avoided by settling"). Thus, for example, if the payment on its face is for some services (and not for avoided litigation costs), the plaintiff might satisfy its pleading burden with facts showing the negative of what the FTC claimed would be evidence of a pro-competitive agreement—e.g., that the terms of the side transaction were not for fair value; that the terms did not comport with industry standards; that there were no previous dealings between the parties on the subject matter of the side transaction; that there was no history of demonstrated interest in or

need for the property or services on the part of the brand-name manufacturer; or that the course and content of the manufacturers' negotiations over the agreements suggested that the purported justification for the agreement was pretextual and that the real reason for the payment was to preserve the brand manufacturer's monopoly. *See id.*; *In re Lipitor Antitrust Litig.*, 868 F.3d at 256 ("To plausibly allege an unjustified reverse payment, an antitrust plaintiff need only allege the absence of a 'convincing justification' for the payment."). Allegations regarding these types of considerations are relevant to whether a reverse-payment agreement is "unjustified." A plaintiff need not "preempt[] every possible explanation" for the reverse payment to survive a motion to dismiss, *Fed. Trade Comm'n v. AbbVie Inc*, 976 F.3d at 356, but a plaintiff must plead at least some facts of this nature to sufficiently allege an unjustified agreement.

With these principles in mind, the Court turns to the allegations of the DPP Complaint.

B. The Alleged Settlement Agreements and Side Agreements

In their motion to dismiss for failure to state a claim, Defendants argue that the settlement agreements and side agreements between Forest and each of the Generic Defendants are not unlawful reverse-payment agreements under *Actavis*. Dkt. No. 269 at 7–40. More specifically, Defendants argue that the settlement agreements, considered separately from the side agreements, include payments for avoided litigation costs and are not large and unexplained. *Id.* at 7–10. Further, they argue that it is not pleaded that the payments associated with the side agreements are related to the decision to settle or that they exceed the fair value of services rendered, are unexplained, or are large. *Id.* at 11–19.

Direct Purchaser Plaintiffs respond that the payments from the settlement agreements and the side agreements together represent large reverse payments and that they allege the payments exceed the fair market value of any goods or services agreed to be provided (though, they maintain, this latter allegation is not required at the pleading stage). Dkt. No. 285 at 15–22.

They also argue that the payments are unexplained and that Defendants have the burden of justifying the reverse payments. *Id.* at 22–24.

The parties first debate whether the complaint plausibly alleges that the settlement agreements and side agreements are related to one another. The Court concludes that the complaint does so. "A settlement agreement may be very simple or tremendously complex, and it may involve all manner of consideration; and if, when viewed holistically, it effects a large and unexplained net transfer of value from the patent-holder to the alleged patent-infringer, it may fairly be called a reverse-payment settlement." *In re Aggrenox Antitrust Litig.*, 94 F. Supp. 3d at 243. Where a plaintiff has plausibly pleaded that several agreements are connected, the Court must accept those allegations as true on a motion to dismiss. *See Fed. Trade Comm'n v. AbbVie Inc*, 976 F.3d at 358 ("Here, the FTC plausibly alleged that AbbVie's settlement with Teva and the TriCor deal were linked. The Court had to accept that allegation as true."); *In re Niaspan Antitrust Litig.*, 42 F. Supp. 3d 735, 752 (E.D. Pa. 2014) ("[D]efendants may not improperly 'dismember' plaintiffs' Consolidated Amended Complaints by examining each of the three settlement agreements in isolation. Rather, the Licensing Agreement must be read in conjunction with the Co-Promotion and Manufacturing Agreements executed that same day." (citations omitted)); *In re Opana ER Antitrust Litig.*, 162 F. Supp. 3d at 718 (disagreeing with defendants' assessment of the components of a settlement "in piecemeal fashion" and instead stating that "[t]he Court must determine whether, when taken as a whole, the total payment" received under the agreements was large and unjustified).

Here, Direct Purchaser Plaintiffs have sufficiently and plausibly alleged that Forest admitted that each settlement agreement and each side agreement was connected to the settlement of the Bystolic patent dispute. The DPP Complaint does not simply assert the

conclusion but instead alleges facts to support that conclusion. In particular, it alleges that outside counsel for Forest, in connection with work on the Forest-Actavis merger, asked for "all of the Bystolic settlement and licensing agreements as well as the side agreements with those generic companies" before counsel engaged in discussions with the FTC. DPP Compl. ¶ 8. Forest responded that it had "side deals" with all of the companies with whom it had settlement agreements. *Id.* ¶¶ 8, 151. In the Forest-Actavis merger agreement, Forest also allegedly listed all of the settlement agreements and the side agreements as material contracts in connection with the settlement of the Bystolic patent dispute. *Id.* ¶¶ 9–17. That allegation, and Forest's characterization of the agreements as "side deals," is sufficient at this stage to support the inference that they are related, particularly given that each of the side agreements was executed in close temporal proximity—sometimes on the same day—with the related settlement agreements.

The Court now turns to the agreements with each of the Generic Defendants to determine whether Direct Purchaser Plaintiffs sufficiently allege that such agreements (the settlement agreement and side deal read together) support the plausible inference of a large and unexplained reverse payment under *Actavis*. The Court analyzes Forest's agreements with each of the Generic Defendants separately by Generic Defendant. Where there are multiple generic manufacturers, it does not follow that simply because a reverse-payment agreement with one Generic Defendant is anticompetitive, the brand manufacturer's agreements with every other Generic Defendant is anticompetitive.[10] Likewise, the fact that one or more reverse-payment

[10] Relatedly, Direct Purchaser Plaintiffs argue that the contingent launch provision in each of the settlement agreements supports joint and several liability for all Defendants if one or more of them have been found liable for agreeing to an unlawful reverse payment. Dkt. No. 285 at 43–45, 44 n.19. To support this argument, Direct Purchaser Plaintiffs rely on tort principles and cite to *In re Modafinil Antitrust Litigation*, 837 F.3d 238 (3d Cir. 2016). This argument is not sound.

agreements a brand manufacturer has with a Generic Defendant is not large or is justified would not establish that no other reverse agreement is anticompetitive. A patent owner who legitimately secures an agreement with one or more potential generic competitors that would prevent the generic from entering the market may still enter an anticompetitive agreement with the remaining potential competitors. As the Supreme Court observed in *Iqbal*, "[d]etermining whether a complaint states a plausible claim for relief will . . . be a context-specific task." *Iqbal*, 556 U.S. at 679.

"Under the doctrine of joint and several liability, '[i]f the tortious conduct of each of two or more persons is a legal cause of harm that cannot be apportioned, each is subject to liability for the entire harm, irrespective of whether their conduct is concurring or consecutive.'" *Id.* at 262 n.29 (alteration in original) (quoting Restatement (Second) of Torts § 879 (1979)). The doctrine requires that each liable person engage in tortious conduct. By analogy, each defendant to be held jointly and severally liable must have engaged in anticompetitive conduct. But Direct Purchaser Plaintiffs seek to hold liable even those that have *not* agreed to an anticompetitive reverse-payment agreement by virtue of a contingent launch provision, which by itself has the effect of increasing competition if activated. Similarly, *In re Modafinil Antitrust Litigation* does not support Direct Purchaser Plaintiffs' conclusion. In that case, which involved similar allegations of reverse-settlement agreements, the defendants appealed the district court's class certification decision. One of the defendants' arguments was that predominance under Rule 23(b)(3) cannot be demonstrated because the plaintiffs' theory of liability must isolate the harm that each individual reverse-payment settlement agreement caused each individual class member under the doctrine of antitrust standing. *Id.* at 261. The defendants argued that the plaintiffs were attempting to circumvent the doctrine of antitrust standing by asserting the theory of joint and several liability. *Id.* at 262. The Third Circuit rejected the defendants' argument and determined that "because all four [generic manufacturers allegedly] entered into these reverse-payment settlement agreements and prevented a competitive market from forming, each contributed to the market-wide harm, and each can be held jointly and severally liable for such harm." *Id.* at 266. Putting aside that this discussion was in the context of a class certification decision, the Third Circuit's conclusion also explicitly relied on all four generic manufacturers allegedly entering into anticompetitive arrangements with the brand manufacturer. In other words, each entity to be held jointly and severally liable had entered into an anticompetitive agreement. By contrast, Direct Purchaser Plaintiffs here, solely based on the competition-increasing contingent launch provisions, attempt to hold liable even those Defendants who are not determined to be parties to anticompetitive reverse-settlement agreements.

1. Hetero

Forest executed the settlement agreement with Hetero to resolve the patent litigation on October 24, 2012. DPP Compl. ¶ 153. In addition to releasing the claims, the agreement included a maximum payment of $200,000 for Forest's avoided litigation fees and Hetero's litigation fees. *Id.*; Dkt. No. 270-1. Hetero also received a license to sell generic Bystolic three months before the patent expired, i.e., September 2021, and agreed to not otherwise manufacture or market any generic equivalent of Bystolic prior to the expiration of the patent. Dkt. No. 270-1.

A few weeks earlier, on October 5, 2012, Forest and Hetero also executed a final term sheet for a supply agreement for [redacted]. DPP Compl. ¶ 153. The final term sheet included a term requiring Forest to [redacted] of the supply agreement to be entered into by the parties. Dkt. No. 270-2. Based on Forest's stated estimate of requirements for [redacted], Forest would allegedly pay Hetero $[redacted] million (before any price adjustments). DPP Compl. ¶ 153; Dkt. No. 270-2. The parties "agree[d] that their respective obligations contained in the 'Obligations' section of this term sheet are effective as of the Term Sheet Date." Dkt. No. 270-2. The Obligations section provides:

> Following execution of this Term Sheet by both Parties:
> - the Parties shall negotiate and enter into the Agreement, which shall contain the terms set forth in this Term Sheet and other terms and conditions that are typical for manufacturing and supply agreements of [redacted];
> - the Parties shall cooperate in good faith to obtain the FDA's approval [redacted]; and

- Forest shall use good faith efforts to amend its current supply agreements with [redacted]. Forest expects full cooperation from [redacted] and that such amendment will be completed together with the completion of the Agreement.

Id.

Direct Purchaser Plaintiffs allege that, prior to the Hetero agreement, Forest had been able to obtain sufficient amount of [redacted] without a supply agreement with Hetero, and that, on information and belief, Forest did not need such an agreement in October 2012. DPP Compl. ¶ 154. They also allege, on information and belief, that the payments under the supply agreement exceeded the fair value of any products or services rendered by Hetero and that the agreement itself was a pretextual conduit of cash from Forest to induce Hetero to agree not to compete in the nebivolol market until September 2021. *Id.*

The alleged $[redacted] million payment that Forest would make to Hetero under the terms of the final term sheet for the supply agreement is large under *Actavis* as it is well beyond any estimated or anticipated avoided litigation costs. The DPP Complaint alleges that Forest's saved litigation costs with respect to each Generic Defendant were far less than $5–6 million; but, even assuming the comparator to be an upper-bound figure of $5–6 million, the alleged reverse payment is large.

Though Direct Purchaser Plaintiffs plead a large reverse payment, they have failed to plead that it is unjustified and have thus not "nudged their claims across the line from conceivable to plausible." *Twombly*, 550 U.S. at 570. The allegations with respect to Hetero squarely raise the questions—also directly presented by the allegations regarding Forest's agreements with the other Generic Defendants—what kinds of allegations should be considered to be "labels and conclusions" or "naked assertion[s]" devoid of further factual enhancement under *Twombly*, *id.* at 555, 557, and to what extent a party can rely on "information and belief"

allegations to satisfy its Rule 8 pleading obligations to state an antitrust claim. The Second Circuit has held that a plaintiff may plead facts "upon information and belief where the facts are peculiarly within the possession and control of the defendant, or where the belief is based on factual information that makes the inference of culpability plausible." *Arista Recs., LLC v. Doe 3*, 604 F.3d 110, 120 (2d Cir. 2010) (internal quotation marks and citations omitted). The allegations that the payments pursuant to the [redacted] supply agreement exceeded the fair value of any products delivered or services rendered by Hetero and that the agreement was a pretextual conduit of cash in exchange for an agreement not to compete, in isolation, are labels and conclusions. They could be asserted in every case in which there is a side agreement with a generic manufacturer who agrees to honor a patent. If those naked allegations were enough to require an answer and to shift the burden to the defendant to prove fair value and the absence of pretext, there would be nothing left of the Supreme Court's rejection of the per se rule in *Actavis*.

The only remaining allegation is that, on information and belief, Forest did not need a supply agreement with Hetero in October 2012 because Forest had been able to obtain sufficient amounts of [redacted] from its existing supplier, [redacted]. It is true that alleging facts regarding the lack of a history of demonstrated interest in or need for the property or service on the part of Forest could raise an inference that the reverse payment is unjustified. But Direct Purchaser Plaintiffs here do not allege such facts. Direct Purchaser Plaintiffs have not pleaded, for instance, that Forest had expressed no interest in entering into a new supply agreement, that Forest was content was its current arrangement with [redacted] that Forest entered this new agreement suddenly and without standard negotiations, or any other facts suggesting something unusual in Forest's new supply agreement with Hetero. Instead, they merely plead, on information and belief, that Forest had no need for the supply agreement based on the

allegation that Forest had been able to obtain sufficient [redacted] in the absence of a new agreement with Hetero. However, the allegation of sufficient existing supply, alone, does not "make[] the inference of culpability plausible." *Arista Recs.*, 604 F.3d at 120. Simply alleging that Forest had been acquiring [redacted] from another source (i.e., [redacted]) is insufficient to raise a plausible inference that Forest had no need for another source of supply or that the [redacted] supply agreement with Hetero is unjustified. Indeed, the fact that Forest had sufficient [redacted] could be entirely consistent with the opposite conclusion from the one offered by Direct Purchaser Plaintiffs—i.e., that Forest was in great need of another supplier. *Cf. Twombly*, 550 U.S. at 554 (finding allegations "consistent with conspiracy, but just as much in line with a wide swath of rational and competitive business strategy" insufficient to state an antitrust claim). Though Forest was obtaining sufficient [redacted], there is nothing pleaded to indicate that Forest was not simultaneously expressing dissatisfaction with its arrangement with [redacted] or actively seeking alternative or supplemental suppliers. Even after drawing all inferences in favor of the non-movant, as the Court must on a motion to dismiss, there is nothing about Forest's sufficient existing supply of [redacted] alone that plausibly pleads an unjustified reverse payment.

Aside from these allegations, the DPP Complaint offers nothing to support why the reverse-payment agreement is unjustified. Direct Purchaser Plaintiffs do not offer any facts alleging, for example: that while Forest agreed to pay $[redacted] million to Hetero for [redacted], Forest could have obtained that same [redacted] from another supplier at a significantly lower price; that the terms of Forest's [redacted] agreement with Hetero were unusual when compared with industry standards; that Forest and Hetero had never had any previous dealings on supply agreements and that Forest had previously expressed no interest in entering into a supply agreement with Hetero; or that the course and content of Forest's negotiations with Hetero revealed a reason why the

agreement would be unjustified. Factual allegations like these might plausibly support that the reverse payment is unjustified. But without further factual enhancement, Direct Purchaser Plaintiffs' allegations remain in "neutral territory" and fall short of stating a claim. *Twombly*, 550 U.S. at 557.

Direct Purchaser Plaintiffs offer several arguments against dismissing their claim with respect to Hetero, but none of these arguments cures their defective pleading. Direct Purchaser Plaintiffs first rebut Defendants' argument that it was a reasonable business decision for Forest to negotiate a possible [redacted] supply agreement with Hetero, [redacted], in order to reduce its dependence on [redacted]. *See* Dkt. No. 285 at 27; *see also* Dkt. No. 269 at 21, 23. Direct Purchaser Plaintiffs are correct that these allegations are not in the DPP Complaint, and thus, the Court cannot credit them on a motion to dismiss. The Court does not rely on Defendants' contrary allegations in holding that Direct Purchaser Plaintiffs' have failed to state a claim. As discussed, the DPP Complaint itself does not provide the factual grounding sufficient to allege an unjustified reverse payment.

Direct Purchaser Plaintiffs are also correct in arguing that Defendants cannot obtain dismissal by asserting that the Hetero supply agreement represented a potential savings for [redacted]. Dkt. No. 285 at 27. Defendants submit a copy of the [redacted] agreement in connection with their motion to dismiss and argue that the terms of this agreement reveal that Forest would have received more favorable price terms under the supply agreement with Hetero than its existing agreement with [redacted].[11] Dkt. No. 269 at 14, 23. In other words, Defendants argue that Forest

[11] As Direct Purchaser Plaintiffs refer to the [redacted] agreement in the DPP Complaint and rely on its effect, the Court may consider it on a motion to dismiss. *See Broder v. Cablevision Sys. Corp.*, 418 F.3d 187, 196 (2d Cir. 2005) ("Where a plaintiff has 'rel[ied] on the terms and effect of a document in drafting the complaint,' and that document is thus 'integral to the complaint,' [the court] may consider its contents even if it is not formally incorporated by reference."

had an "economically rational incentive" to enter in the supply agreement envisioned by the term sheet. *Id.* at 14. Defendants contend that the final term sheet with Hetero represents a potential savings in the purchase of [redacted] because the term sheet shows that Forest would initially be paying [redacted] while the [redacted] agreement required Forest to pay up to a maximum of [redacted]. *Id.* at 23. But the [redacted] agreement contains a cap on what Forest would be required to pay; neither the [redacted] agreement nor the DPP Complaint reveals what Forest actually paid or was expecting to pay [redacted]. Without this information, Defendants' argument that the [redacted] agreement on its face discredits any allegation of overpayment is without merit.

Direct Purchaser Plaintiffs are also correct that the unfinalized nature of the final term sheet does not stand as a barrier to stating a claim. Dkt. No. 285 at 28–29. Defendants highlight that the side deal was reflected only in a final term sheet but not in a finalized supply agreement. Dkt. No. 269 at 21–22. According to Defendants, the final term sheet merely described the terms of a potential supply agreement, which was contingent on the response of an unrelated third party ([redacted]), FDA approval for use of Hetero's supply, and finalizing the agreement. *Id.* However, Defendants do not dispute that the term sheet created obligations on Forest (as well as on Hetero) and that those obligations had value. The term sheet obligated the parties to: (1) negotiate and enter into a finalized supply agreement containing the terms of the term sheet—including the [redacted] pricing and quantity terms allegedly amounting to $[redacted] million in payments from Forest to Hetero; (2) "cooperate in good faith to obtain the FDA's approval or deemed approval" for use of Hetero's [redacted] in Bystolic; and (3) "use good faith efforts to amend its current supply

(alteration in original) (quoting *Chambers v. Time Warner, Inc.*, 282 F.3d 147, 153 (2d Cir. 2002))).

agreements with [ ] to permit Forest to meet the Purchase Minimum." Dkt. No. 270-2. Thus, at a minimum, the final term sheet appears to constitute a preliminary agreement of the Type II variety, which "creates an 'obligation to negotiate the open issues in good faith in an attempt to reach the [ultimate contractual objective] within the agreed framework.'" *Brown v. Cara*, 420 F.3d 148, 157 (2d Cir. 2005) (alteration in original) (quoting *Tchrs. Ins. & Annuity Ass'n of Am. v. Trib. Co.*, 670 F. Supp. 491, 498 (S.D.N.Y. 1987)). The final term sheet thus created an obligation to negotiate a finalized agreement, "which shall contain the terms set forth in this Term Sheet." Dkt. No. 270-2. "An allegation of an actionable reverse-payment settlement, however, does not require an enforceable contract." *In re Solodyn (Minocycline Hydrochloride) Antitrust Litig.*, 2015 WL 5458570, at *9 (citing *Am. Tobacco Co. v. United States*, 328 U.S. 781, 809 (1946), for the proposition that "[n]o formal agreement is necessary to constitute an unlawful conspiracy"). Even if the term sheet here did not itself bind Forest to the ultimate contractual goal, it did obligate Forest to "negotiate and enter into a finalized supply agreement" that would include the pricing and quantity terms amounting to $ million in payments from Forest to Hetero. The fact that final papers were not yet documented and signed does not itself prevent the agreement the parties did reach from being considered anticompetitive under *Actavis*. *See id.* (rejecting argument that lack of legal commitment and requirement that parties negotiate in good faith to reach a definitive licensing and partnership agreement is insufficient to state a claim under *Actavis*).

In any event, Direct Purchaser Plaintiffs cannot overcome their failure to plead that the large reverse payment is unjustified. For that reason, the Court holds that Direct Purchaser Plaintiffs have failed to state a claim with respect to the Hetero agreements.

2. Torrent

Forest's settlement agreement with Torrent was executed on November 21, 2012, and, in addition to releasing the claims, the agreement granted Torrent a license to sell generic Bystolic three months before patent expiration, i.e., September 2021; obligated Torrent to not otherwise manufacture or market any generic equivalent of Bystolic before the patent expired; and included a payment of up to $1 million from Forest to Torrent for Torrent's expended litigation fees and in partial consideration of Forest's saved legal fees. DPP Compl. ¶ 156; Dkt. No. 270-12. On the same day, Forest and Torrent executed a patent assignment agreement under which Forest agreed to purchase ten patents related to manufacturing nebivolol for a non-refundable, upfront payment of $[redacted] million plus an additional $[redacted] million in milestone payments, for a total of $[redacted] million. DPP Compl. ¶ 156; Dkt. No. 270-13. Direct Purchaser Plaintiffs allege that the conditions of the milestone payments were not difficult to satisfy. DPP. Compl. ¶ 157. They also allege that, because Forest had manufactured and marketed nebivolol in the United States and other jurisdictions without licenses from Torrent, Forest already had all of the intellectual property that it needed to successfully manufacture and sell Bystolic, and thus the Torrent patents had little or no value to Forest. *Id.* ¶ 158. They allege, on information and belief, that Forest knew about Torrent's patents prior to the patent assignment agreement, and only executed the patent assignment agreement in exchange for Torrent's agreement to refrain from marketing generic Bystolic until September 2021. *Id.* They further allege, on information and belief, that the payments related to the patent assignment agreement exceeded the fair value of any products delivered or services rendered by Torrent and that the agreement itself was a pretextual conduit of cash from Forest to induce Torrent not to compete in the nebivolol market until September 2021. *Id.*

The alleged payment from Forest to Torrent under the patent assignment agreement represents a large reverse payment. In exchange for ten patents, the agreement allegedly provided for a $[redacted] million payment and an additional $[redacted] million in milestone payments, which were allegedly easy to achieve, for a total of $[redacted] million—significantly larger than Forest's saved litigation costs, which are pleaded to be less than $5–6 million. This is so even assuming the saved litigation costs are in the range of $5–6 million. Defendants' arguments to the contrary are not persuasive. Defendants argue that the DPP Complaint does not allege that payments were actually made under the patent assignment agreement. Dkt. No. 269 at 32. But the thrust of the DPP Complaint's allegation is that Forest and Torrent entered into an agreement that binds Forest to make such payments to Torrent. Defendants also argue that the maximum possible payment of $[redacted] million corresponds to $[redacted] million per patent, which is not large. *Id.* But Defendants cite no authority supporting their methodology of dividing the total alleged payment into certain smaller units before determining whether a payment is large. Courts, in fact, favor reviewing the total payment received by a generic manufacturer under an agreement "as a whole" rather than reviewing the components of the agreement "in piecemeal fashion." *In re Opana ER Antitrust Litig.*, 162 F. Supp. 3d at 718; *see In re Aggrenox Antitrust Litig.*, 94 F. Supp. 3d at 243 ("A settlement agreement may be very simple or tremendously complex, and it may involve all manner of consideration; and if, *when viewed holistically*, it effects a large and unexplained net transfer of value from the patent-holder to the alleged patent-infringer, it may fairly be called a reverse-payment settlement." (emphasis added)). Direct Purchaser Plaintiffs have therefore alleged enough to plead a large reverse payment under *Actavis*.

As with the DPP Complaint's allegations regarding the Hetero agreements, however, the allegations about the Torrent agreements fall short of the requirement that the allegedly large

reverse payment be unexplained or unjustified. As with the Hetero agreements, the Court does not credit or rely upon the conclusory allegation here that the payments related to the patent assignment agreement exceeded the fair value of any products delivered or services rendered by Torrent and that the agreement was a pretextual conduit of cash from Forest to induce Torrent not to compete. Additionally, the allegation, pleaded on information and belief, that Forest only executed the patent assignment agreement in exchange for Torrent's agreement to refrain from marketing generic Bystolic until September 2021 is similarly conclusory. All that remains are the allegations that the Torrent patents had little or no value to Forest because Forest had been able to successfully manufacture and sell Bystolic without that intellectual property and that, on information and belief, Forest knew about Torrent's patents before executing the patent assignment agreement. But, for reasons analogous to the ones given above with respect to the Hetero allegations, these allegations cannot plausibly support that the large reverse payment is unjustified. It does not plausibly follow that, because Forest had been able to manufacture and sell Bystolic, the Torrent patents had little or no value to Forest; there is a missing link between the first statement and the conclusion of no value. If the DPP Complaint contained factual allegations to support that the Torrent patents had little or no value to Forest, the DPP Complaint would then speak to the absence of bona fide fair consideration for the patents and the lack of Forest's need for these patents, both of which suggest the existence of an unjustified reverse payment. But what is pleaded is deficient.

Again, Direct Purchaser Plaintiffs could have, for example, pleaded facts: independently estimating the value of the patents; explaining why this patent assignment agreement did not comport with industry standards; showing that there had not been any previous dealings or discussions between Forest and Torrent on these patents; demonstrating that Forest had

previously expressed no interest in these patents; or describing negotiations that were out of the ordinary for such patent assignment agreements. Such facts might plausibly plead that the large reverse payment is unjustified here. In fact, in their memorandum of law opposing Defendants' motion, Direct Purchaser Plaintiffs argue that "having sold billions of dollars' worth of Bystolic without the use of Torrent's patents, it is not plausible that Forest would reformulate the product at the end of its lifecycle." Dkt. No. 285 at 30. This assertion—reflecting why the patent assignment agreement may depart from standard industry practice—gets closer to the type of factual allegations that might be sufficient to show that the agreement is unjustified. But the DPP Complaint does not contain this allegation, and "[i]t is axiomatic that the Complaint cannot be amended by the briefs in opposition to a motion to dismiss." *Cambridge Cap. LLC v. Ruby Has LLC*, 2021 WL 4481183, at *19 n.11 (S.D.N.Y. Sept. 30, 2021) (alteration in original) (internal quotation marks omitted) (quoting *United States ex rel. Foreman v. AECOM*, 454 F. Supp. 3d 254, 268 (S.D.N.Y. 2020)); *see also Soules v. Connecticut, Dep't of Emergency Servs. & Pub. Prot.*, 882 F.3d 52, 56 (2d Cir. 2018) ("Ordinarily, parties may not amend the pleadings through motion papers."). Thus, as pleaded, the DPP Complaint is lacking.

Direct Purchaser Plaintiffs argue that the Court may not rely on Defendants' narrative that such patent assignment agreements are "*de rigueur*" and that the patents covered a process that could be valuable to Forest and its customers. Dkt. No. 285 at 29–30. Direct Purchaser Plaintiffs are correct that such allegations by the movant are not included in the DPP Complaint and are thus not properly before the Court on a motion to dismiss. The Court does not credit Defendants' allegations in finding the DPP Complaint wanting. Rather, it falls short for not pleading facts regarding why the large reverse payment is unjustified.

The Court therefore holds that Direct Purchaser Plaintiffs have failed to state a claim with respect to the Torrent agreements.

3. Alkem/Indchemie

Forest executed settlement agreements with Alkem and Indchemie on November 27, 2012, which granted them licenses to sell generic Bystolic three months before patent expiration, i.e., September 2021, and obligated them to not otherwise manufacture or market any generic Bystolic before expiration of the patent. Dkt. Nos. 270-7, 270-8. The settlement agreement with Alkem also included a $1 million payment for a portion of Forest's avoided legal fees and Alkem's litigation fees. DPP Compl. ¶ 159; Dkt. No. 270-7. The next day, Forest and Alkem/Indchemie executed a term sheet pursuant to which Alkem/Indchemie agreed to supply Forest with two finished drug products—[redacted]. DPP Compl. ¶ 159. Under the term sheet, Forest agreed to pay Alkem/Indchemie a total of at least $[redacted] million, including:

- An upfront payment of $[redacted] million [redacted];
- Milestone payments up to $[redacted] million, contingent upon the completion of certain steps in the development of each product, but with Forest required to pay any of the milestone payments if the completion of the corresponding milestone(s) was delayed by [redacted];
- [redacted];
- A commitment to purchase a minimum of [redacted]; and
- A $[redacted] million [redacted].

Id.

At the time the term sheet was executed, Direct Purchaser Plaintiffs allege that Forest had not yet submitted its NDA for [redacted] and that the NDA was not submitted until February 2014. *Id.* ¶ 160. They allege, on information and belief, that submission of the NDA in February 2014 would have triggered the delay provision and therefore required Forest to make the milestone payments to Alkem/Indchemie associated with Byvalson. *Id.* Direct Purchaser Plaintiffs also claim, on information and belief, that, prior to the term sheet, Forest had no need for a supply agreement for Bystolic and that Forest had expressed no interest in working with Alkem/Indchemie on [redacted]. *Id.* ¶ 161. And they allege, again on information and belief, that the payments pursuant to the term sheet exceeded the fair value of any products delivered or services rendered by Alkem/Indchemie and that the agreement itself was a pretextual conduit of cash from Forest to induce Alkem/Indchemie not to compete in the nebivolol market until September 2021. *Id.*

With respect to the agreements between Forest and Alkem/Indchemie, the DPP Complaint does not state a claim under *Actavis*. While the pleading plausibly alleges a large reverse-payment agreement (the alleged $[redacted] million reverse payment as compared to the pleaded less than $5–6 million in avoided litigation costs), it provides no factual support for the contention that the large reverse payment is unexplained or unjustified. The allegation—recited verbatim with respect to Forest's agreements with each of the Generic Defendants—that the payments under the term sheet exceeded the fair value of any products delivered or services rendered by Alkem/Indchemie is conclusory and a "label" insufficient alone to state a claim. Direct Purchaser Plaintiffs do allege that, prior to entering into the term sheet, Forest had no need for a supply agreement for [redacted] and had not expressed an interest in working with Alkem/Indchemie on [redacted]. DPP Compl. ¶¶ 160–161. But these allegations—which might

be sufficient if supported by fact—are alleged only on information and belief. Direct Purchaser Plaintiffs assert no facts to support the claim that Forest had no need for additional products or services from Alkem and/or Indchemie to support anticipated market demand for [redacted] products. *See Brodie v. Green Spot Foods, LLC*, 503 F. Supp. 3d 1, 13 (S.D.N.Y. 2020) ("When allegations are made upon information and belief, the plaintiff must support them by offering facts upon which that belief is founded."). Nor are the facts to support this claim in the exclusive possession of Defendants. They further do not allege facts to support that, prior to signing the settlement agreements and term sheet with Alkem/Indchemie, Forest had expressed no interest in an agreement with those companies. This cannot be enough to satisfy *Actavis.* It is not enough that two parties entered into a new agreement at the same time as they settled the patent litigation for a reverse payment; the plaintiff must allege that there is something about that agreement other than its timing and the fact that it results in the generic manufacturer honoring a patent that supports the inference that it is anticompetitive.

For these reasons, Defendants' motion to dismiss is granted with respect to the Alkem/Indchemie agreements for failure to state a claim.

4. Glenmark

Forest executed its settlement agreement with Glenmark on December 21, 2012, and the agreement included a payment of up to $1.2 million to Glenmark for a portion of Forest's avoided legal fees and Glenmark's litigation costs. DPP Compl. ¶ 163; Dkt. No. 270-14. The agreement also granted Glenmark a license to sell generic Bystolic three months before patent expiration, i.e., September 2021, and bound Glenmark to not otherwise manufacture or market any generic Bystolic before patent expiration. Dkt. No. 270-14. The same day that the settlement agreement was executed, Forest and Glenmark executed a collaboration and option agreement under which the two companies would jointly develop [redacted]

[redacted] products for at least [redacted] absent earlier termination and Forest would pay Glenmark $[redacted] million in upfront and milestone payments. *Id.* The $[redacted] million in payments included an upfront payment of $[redacted] million, which consisted of:

- A $[redacted] million [redacted] and
- A $[redacted] million [redacted]

Id. The additional $[redacted] million in payments included: $[redacted] million [redacted]; and $[redacted] million [redacted]. *Id.* All intellectual property developed by Glenmark in connection with [redacted] remained exclusively with Glenmark except for Forest's option for a right of first negotiation of an exclusive license to use the technology. *Id.*

Direct Purchaser Plaintiffs further allege, on information and belief, that prior to executing the agreements, Forest had expressed no interest to Glenmark concerning Glenmark's development of [redacted]. *Id.* ¶ 164. They also allege, on information and belief, the payments under the collaboration and option agreement exceeded the fair market value of any products delivered or services rendered by Glenmark. *Id.*

Direct Purchaser Plaintiffs' allegations regarding the Glenmark agreements suffer from the same deficiencies as their allegations regarding the Alkem/Indchemie agreements. Though they have plausibly alleged a large reverse payment—$[redacted] million in payments as compared to the alleged less than $5–6 million in avoided legal fees—they have failed to offer any factual allegations for why the allegedly large reverse payment is unexplained or unjustified. First, as

with the other agreements, the allegation that the payments under the collaboration and option agreement exceeded the fair value of Glenmark's products or services is simply a conclusory allegation that cannot support whether Direct Purchaser Plaintiffs have plausibly stated a claim under *Actavis*. Second, it is true that Direct Purchaser Plaintiffs allege, on information and belief, that Forest had previously expressed no interest in Glenmark's development of [redacted]. And factual allegations of this type relate to whether a reverse-payment agreement is unjustified because they shed light on whether there exists a history of demonstrated interest in or need for the property or services. *See supra* Section I.A. But, as discussed in relation to Alkem/Indchemie, *supra* Section I.B.3, all facts about Forest's interest in Glenmark's development of [redacted] are not within the exclusive possession of Defendants, and Direct Purchaser Plaintiffs have provided no factual basis for their belief that Forest had expressed no such interest prior to the agreement. Thus, this allegation pleaded on information and belief without any additional factual basis cannot plausibly support the claim that the reverse-payment agreement is unjustified.

For these reasons, Defendants' motion to dismiss is granted with respect to the Glenmark agreements for failure to state a claim.

5. Amerigen

The Forest-Amerigen settlement agreement was executed on July 18, 2013. DPP Compl. ¶ 165. Pursuant to the agreement, Amerigen was granted a license to sell generic Bystolic three months before patent expiration, i.e., September 2021, and agreed to not otherwise manufacture or market generic Bystolic before patent expiration. Dkt. No. 270-17. The agreement also included a payment of $2 million to Amerigen for a portion of Forest's saved litigation fees and Amerigen's litigation fees. DPP Compl. ¶ 165; Dkt No. 270-17. On the same day this settlement agreement was executed, Forest and Amerigen executed a binding term sheet

collaboration agreement under which Forest agreed to invest in the development of eight Amerigen products. DPP Compl. ¶ 165. This agreement included a non-refundable, upfront payment of $[redacted] million plus $[redacted] million in milestone payments contingent upon certain product development and launch events. *Id.* The agreement also included an option for Forest to commercialize up to eight Amerigen products in Latin America and South America, which Amerigen had the right to supply to Forest for its manufacturing costs plus [redacted], and on other customary and reasonable terms. *Id.*

Direct Purchaser Plaintiffs allege, on information and belief, that prior to executing the settlement and collaboration agreements, Forest had expressed no interest in Amerigen's products and that the payments under the collaboration agreement exceeded the fair value of any products delivered or services rendered by Amerigen. *Id.*

With respect to the Amerigen agreements, Direct Purchaser Plaintiffs fail to state a claim under *Actavis* for the same reasons they did not state a claim regarding the Alkem/Indchemie and Glenmark agreements. They again plausibly allege a large reverse payment—$[redacted] million in payments as compared to the pleaded figure of less than $5–6 million in avoided legal fees—but they do not allege facts to support the claim that the large reverse-payment agreement is unjustified. Akin to their pleadings with respect to the Alkem/Indchemie and Glenmark agreements, Direct Purchaser Plaintiffs offer only conclusory allegations on information and belief that relate to whether there was bona fide fair consideration for the property or services and whether there was a history of demonstrated interest in or need for the property or services on the part of the brand manufacturer. Without factual allegations on these points, there are not enough factual allegations to plausibly state a claim of a large and unjustified reverse-payment agreement under *Actavis*.

For these reasons, Defendants' motion to dismiss is granted with respect to the Amerigen agreements for failure to state a claim.

6. Watson

Forest executed a settlement agreement with Watson on November 6, 2013; the agreement granted Watson a license to sell generic Bystolic three months before patent expiration, i.e., September 2021; obligated Watson to not otherwise manufacture or market generic Bystolic prior to patent expiration; and included a payment of up to $2 million to Watson in partial consideration of Forest's saved litigation fees and Watson's litigation fees. DPP Compl. ¶ 166; Dkt. No. 270-4. Shortly before this settlement agreement was executed, Forest and Watson entered into a series of agreements related to Moksha8, Inc. ("Moksha8"), a Brazilian startup drug manufacturer with which both Forest and Watson were involved in equity investment or financing transactions. DPP Compl. ¶ 166 & n.95. Under those agreements, Forest agreed to extend financing to Moksha8 despite Moksha8's failure to meet existing loan conditions; Watson's agreements with Moksha8 were terminated; Watson agreed to pay $[redacted] million to Moksha8; and Watson received releases of potential claims by Moksha8. *Id.* ¶¶ 166–168.

More specifically, in a November 1, 2013 letter agreement, Forest agreed to make $[redacted] million in loan amounts available to Moksha8. *Id.* ¶¶ 166–167. Forest was not obligated to make any loans or any other extensions of credit to Moksha8 because Moksha8 failed to meet certain loan conditions. *Id.* ¶ 167. But in exchange for a release, Forest agreed to make a portion of certain loans available to Moksha8. *Id.* Additionally, three days later, on November 4, 2013, Watson and Moksha8 executed a termination and release agreement. *Id.* ¶ 166. This agreement terminated certain contractual relationships between Watson and Moksha8 including, for example, [redacted], and

[redacted]. *Id.* ¶¶ 166, 168. In exchange for Watson paying $[redacted] million to Moksha8, the agreement also included mutual releases of claims arising out of these terminated agreements, as well as of claims in any way related to the transactions contemplated by an [redacted]. *Id.*

Direct Purchaser Plaintiffs plead, on information and belief, that the value of these broad releases exceeded any consideration that Watson paid for the releases. *Id.* ¶ 166. They also allege, on information and belief, that the transactions in early November 2013 involving Forest, Watson, and Moksha8—including specifically Moksha8's release of all claims against Watson arising out of the [redacted]—disguised significant payments from Forest to Watson through the Moksha8 venture that exceeded Watson's $[redacted] million payment and the fair value of any other products delivered or services rendered by Watson in connection with those agreements. *Id.* ¶ 169.

As a threshold matter, the Court considers the settlement agreement, the Forest-Moksha8 letter agreement, and the Watson-Moksha8 termination and release agreement together. Defendants argue that there are no facts connecting Forest's loan to Moksha8 with the separate agreement entered between Moksha8 and Watson aside from rough temporal proximity. Dkt. No. 269 at 26. But there is more alleged than rough temporal proximity. As discussed, *see supra* Section I.B, the DPP Complaint alleges that Forest admitted that all of the settlement agreements related to the Bystolic litigation had side agreements and that, as part of an unrelated merger transaction, Forest listed these three agreements as material contracts in connection with settling the Bystolic patent dispute. DPP Compl. ¶¶ 17, 151.

Even considering these three agreements together, however, the Court determines that Direct Purchaser Plaintiffs have not sufficiently pleaded the existence of a reverse payment—that is, a payment from Forest to Watson. Forest allegedly extended to Moksha8 a "payment," i.e., something of value, in making loan funds available to Moksha8 even though Moksha8 did not meet certain loan criteria. *See In re Aggrenox Antitrust Litig.*, 94 F. Supp. 3d at 243 ("I must conclude that large and unjustified reverse payments that 'can bring with [them] the risk of significant anticompetitive effects' can bring those effects regardless of the particular form the transfer of value takes and thus are not limited to cash payments." (alteration in original) (citation omitted)); *In re Actos End Payor Antitrust Litig.*, 2015 WL 5610752, at *13 ("The majority view [is] that *Actavis*'s holding is not limited to payments made in cash. This view is consistent with traditional understandings of the term 'payment,' which is defined in Black's Law Dictionary as the '[p]erformance of an obligation by the delivery of money *or some other valuable thing* accepted in partial or full discharge of the obligation.'" (alteration in original) (citations omitted)). But the complaint notably lacks factual allegations regarding how that transfer of value, or "payment," to Moksha8 was then conveyed to Watson, thereby constituting a reverse payment from Forest to Watson through intermediary Moksha8. The best Direct Purchaser Plaintiffs can do is plead, on information and belief, that Moksha8's release of all claims against Watson was more valuable than any consideration Watson paid for the releases. In other words, Direct Purchaser Plaintiffs appear to be alleging that the "payment" from Forest to Moksha8 was then passed on from Moksha8 to Watson through an imbalanced exchange of value in the termination and release agreement. They allege as much on information and belief; namely, they allege, on information and belief, that the transactions in early November 2013 involving Forest, Watson, and Moksha8 disguised significant payments from Forest to Watson

through the Moksha8 venture that exceeded Watson's $[redacted] million payment and the fair value of any other products delivered or services rendered by Watson in connection with those agreements. But these allegations are entirely conclusory and cannot serve to plausibly support Direct Purchaser Plaintiffs' claim. Indeed, the caveat in the conclusory allegation that the value of the releases exceeded Watson's $[redacted] million payment highlights how Watson actually paid Moksha8 a sum of money as part of the agreement, which goes in the opposite direction from the alleged reverse payment from Forest through intermediary Moksha8 toward Watson. Aside from these conclusory allegations, there are no facts in the DPP Complaint to raise a plausible inference that the releases were relatively more valuable than the $[redacted] million and other consideration rendered by Watson to Moksha8. For example, the DPP Complaint could have included facts describing the releases, explaining why the releases were valuable to Watson, and providing context to estimate their relative value even if precise estimates are not alleged. Absent facts of that nature or other facts, Direct Purchaser Plaintiffs are missing a link in their theory and have failed to plead the existence of a reverse payment from Forest to Watson.

Direct Purchaser Plaintiffs argue that Forest itself characterized the Moksha8 transaction as a side deal with Watson that involved the exchange of at least $15 million in connection with the Bystolic patent settlement. Dkt. No. 285 at 34. But Direct Purchaser Plaintiffs overread the scope of Forest's admission. It is true that, as part of an unrelated merger agreement, Forest disclosed its material contracts and listed the agreements involving Watson and Moksha8 as material contracts in connection with the settlement of the Bystolic patent dispute. "Material contracts" were defined to include:

> any Contract involving the settlement of any action or threatened action (or series of related actions) (A) which will (x) involve payments after the date hereof of consideration in excess of $15,000,000 or (y) impose monitoring or reporting obligations to any other Person outside the ordinary course of business or (B) with

> respect to which material conditions precedent to the settlement have not been satisfied.

DPP Compl. ¶ 9. Direct Purchaser Plaintiffs argue that inclusion in this list of material contracts indicates that the agreements involved payments in excess of $15 million. But with this interpretation, they mischaracterize the inclusion criteria and focus on only one of the three disjunctive criteria for disclosure as a material contract. The DPP Complaint does not plead any facts to plausibly tip the scales away from the other inclusion criteria in favor of the one indicating that the agreement involved payments over $15 million. As discussed, Forest's admission indicates that the various agreements are related to the settlement of the Bystolic litigation and that they should be considered together, as the Court has done. Forest's admission, however, does not automatically show that there was a payment in excess of $15 million from Forest to Watson.

For the reasons given, Defendants' motion to dismiss with respect to the Watson agreements is granted.

C. Defendants' Remaining Arguments

Since the Court dismisses Direct Purchaser Plaintiffs' claims as to all Defendants, the Court need not reach Defendants' remaining arguments for dismissal: that Direct Purchaser Plaintiffs improperly group the thirty-two Defendants into ten corporate families and fail to offer individual facts to support claims against a couple particular Defendants; that Direct Purchaser Plaintiffs' theories of causation fail as a matter of law; and that Direct Purchaser Plaintiffs' construction of the Sherman Act's reach under *Actavis* violates Defendants' due process rights.

On causation, the Court notes only that Defendants do not provide an independent ground for dismissal. Direct Purchaser Plaintiffs allege three theories of causation—namely that but for the alleged reverse-payment agreements, Generic Defendants would have launched their less

expensive generic versions of Bystolic earlier than September 17, 2021: (1) at risk during pendency of the Nebivolol Patent Litigation; (2) upon prevailing against Forest in the Nebivolol Patent Litigation; or (3) via lawful, procompetitive settlement agreements providing for earlier negotiated entry dates untainted by the delay caused by the unlawful reverse payments. DPP Compl. ¶ 174. Defendants argue that the first two theories are too speculative as a matter of law and that the at-risk launch theory fails to account for the regulatory bar on generic launch before June 2015. Dkt. No. 269 at 45–50. Defendants further argue that the third causation theory is precluded by the Hetero settlement because that settlement provides what the earliest entry date would be. *Id.* at 50–52. Putting aside Defendants' arguments with respect to the first two causation theories, the Court observes that Defendants' argument about Direct Purchaser Plaintiffs' third causation theory assumes that the agreements settling the litigation with Hetero involved a small and justified reverse payment. In other words, this argument relies on the allegations about Hetero failing to meet the *Actavis* standard and does not provide an independent ground of dismissal.

The Court also need not address defendant Teva Israel's motion to dismiss the DPP Complaint for lack of personal jurisdiction. The Second Circuit has stated that "[a]lthough we traditionally treat personal jurisdiction as a threshold question to be addressed prior to consideration of the merits of a claim, that practice is prudential and does not reflect a restriction on the power of the courts to address legal issues." *ONY, Inc. v. Cornerstone Therapeutics, Inc.*, 720 F.3d 490, 498 n.6 (2d Cir. 2013) (citation omitted). In cases involving "multiple defendants—over some of whom the court indisputably has personal jurisdiction—in which all defendants collectively challenge the legal sufficiency of the plaintiff's cause of action, we may address first the facial challenge to the underlying cause of action and, if we dismiss the claim in

its entirety, decline to address the personal jurisdictional claims made by some defendants." *Chevron Corp. v. Naranjo*, 667 F.3d 232, 247 n.17 (2d Cir. 2012). Accordingly, having dismissed the claims in their entirety, the Court declines to address Teva Israel's arguments on personal jurisdiction. *See, e.g.*, *Chen v. China Green Agric. Inc.*, 2021 WL 4481045, at *4 (S.D.N.Y. Sept. 30, 2021) ("Because the Court finds that the Amended Complaint does not make out a claim for which relief can be granted, and dismisses the case in its entirety, it does not address the personal jurisdiction arguments."); *Fratelli BVBA v. APM Music Servs., LLC*, 2021 WL 4429417, at *6 (S.D.N.Y. Sept. 27, 2021) ("Because dismissal of the unjust enrichment claims terminates All Parts from this action, the Court does not address its argument for dismissal for lack of personal jurisdiction."); *Oklahoma L. Enf't Ret. Sys. v. Telefonaktiebolaget LM Ericsson*, 2020 WL 127546, at *9 (S.D.N.Y. Jan. 10, 2020) ("The Court need not and does not reach Defendants' other arguments for dismissal, including their contention that the Court lacks personal jurisdiction over individual Defendant Mellander." (citing *ONY*, 720 F.3d at 498 n.6)); *LLM Bar Exam, LLC v. Barbri, Inc.*, 271 F. Supp. 3d 547, 574 n.8 (S.D.N.Y. 2017), *aff'd,* 922 F.3d 136 (2d Cir. 2019) ("The Court plainly has personal jurisdiction over, for example, the New York Law Schools. Thus, even if the Court were to hold that it lacks personal jurisdiction over the Non-New York Law Schools, it would have to consider their merits arguments about the First Amended Complaint, which arguments are identical to those of the New York Law Schools. Instead of adopting that piecemeal approach, the Court will dismiss the First Amended Complaint as to all Defendants under Rule 12(b)(6).").

* * *

The Court therefore dismisses Direct Purchaser Plaintiffs' Complaint and Retailer Plaintiffs' Complaints without prejudice. The Court is not aware of any request by Direct

Purchaser or Retailer Plaintiffs to replead if their complaints are dismissed, but "[i]t is within the Court's discretion to *sua sponte* grant leave to amend." *Safe Step Walk in Tub Co. v. CKH Indus., Inc.*, 242 F. Supp. 3d 245, 271 (S.D.N.Y. 2017). The Second Circuit "strongly favors liberal grant of an opportunity to replead after dismissal of a complaint under Rule 12(b)(6)." *Porat v. Lincoln Towers Cmty. Ass'n*, 464 F.3d 274, 276 (2d Cir. 2006). Federal Rule of Civil Procedure 15(a)(2) provides that the Court "should freely give leave when justice so requires." Fed. R. Civ. P. 15(a)(2). "A district court has discretion to deny leave for good reason, including futility, bad faith, undue delay, or undue prejudice to the opposing party," *McCarthy v. Dun & Bradstreet Corp.*, 482 F.3d 184, 200 (2d Cir. 2007), and "[t]he decision to grant leave to amend is within the sound discretion of the trial court," *Bay Harbour Mgmt., LLC v. Carothers*, 474 F. Supp. 2d 501, 502 (S.D.N.Y. 2007). Because Direct Purchaser and Retailer Plaintiffs did not previously have the benefit of the Court's views, because the Court cannot say that any amendment would be futile, and because this Circuit favors an opportunity to replead after dismissal under Rule 12(b)(6), the Court grants Direct Purchaser Plaintiffs and Retailer Plaintiffs leave to amend their complaints.

II. Motions Regarding End-Payor Plaintiffs' Complaint

The Court now turns to the motions to dismiss End-Payor Plaintiffs' Complaint. "Under the United States Supreme Court's decision in *Illinois Brick Co. v. Illinois,* 431 U.S. 720, 745–46 (1977), indirect purchasers of products sold at supra-competitive prices lack standing to sue under federal antitrust statutes. However, under its later decision in *California v. ARC Am. Corp.*, 490 U.S. 93, 105–06 (1989), indirect purchasers may still bring suit under state antitrust laws, if a state permits such claims." *Sergeants Benevolent Ass'n Health & Welfare Fund v. Actavis, plc*, 2018 WL 7197233, at *1 (S.D.N.Y. Dec. 26, 2018). "Therefore, it is common in private antitrust litigation for two groups of purchasers, direct and indirect, to file separate cases

arising out of the same nucleus of operative fact, but to allege different causes of action—direct purchasers under federal law and indirect purchasers under state laws." *Id.* As a district court in this Circuit has observed, "[t]he problem for the indirect purchasers is that the indirect-purchaser rule of *Illinois Brick* blocks them from recovery under federal antitrust law," and, therefore, "[i]n an effort to get in on the *Actavis* game, they attempt to build a Frankensteinian equivalent of *Actavis* to reach the very same conduct but without that formidable obstacle, by stitching together a hodge-podge of state-law claims." *In re Aggrenox Antitrust Litig.*, 94 F. Supp. 3d at 255. End-Payor Plaintiffs have done just that here.

Based on the same factual allegations of the DPP Complaint, End-Payor Plaintiffs bring 101 state-law claims. In particular, End-Payor Plaintiffs allege: claims for monopolization and monopolistic scheme against Forest under the antitrust laws of twenty-three states; claims for conspiracy to monopolize against all Defendants under the antitrust laws of twenty-seven states; claims for combination and conspiracy in restraint of trade against all Defendants under the antitrust laws of twenty-seven states; and claims for unfair or deceptive trade practices against all Defendants under the consumer-protection laws of twenty-four states.[12] EPP Compl. ¶¶ 290–452.

Because the Court dismisses the federal antitrust claims, however, End-Payor Plaintiffs' claims under the antitrust laws of various states—based on the same factual allegations—fail too. *See, e.g.*, *In re Tamoxifen Citrate Antitrust Litig.*, 277 F. Supp. 2d 121, 139 (E.D.N.Y. 2003), *aff'd,* 466 F.3d 187 (2d Cir. 2006) ("[S]ince Plaintiffs fail to state a claim under the

[12] End-Payor Plaintiffs withdrew their claim under the Virginia Consumer Protection Act. Dkt. No. 286 at 12 n.30. End-Payor Plaintiffs also bring a claim for injunctive relief under the federal antitrust laws. EPP Compl. ¶¶ 453–457. The Court dismisses the End-Payor Plaintiffs' claim under the federal antitrust laws for the same reasons it dismisses the DPP Complaint's federal antitrust claims.

Sherman Act, and since the state antitrust law claims are based on the same allegations, those claims are also dismissed."); *In re Androgel Antitrust Litig. (No. II)*, 687 F. Supp. 2d 1371, 1382 (N.D. Ga. 2010) ("Because the Plaintiffs' allegations do not state a plausible antitrust claim under federal law, the Indirect Purchasers also do not state a plausible antitrust claim under state law."). In a footnote in their opposition to Defendants' motion to dismiss, End-Payor Plaintiffs argue that it is "overstated" to say that *Actavis* controls the interpretation of all state antitrust laws. Dkt. No. 286 at 3 n.4. But End-Payor Plaintiffs have not explained the ways in which the various state antitrust laws differ from federal antitrust law and how those differences would apply to the facts alleged here. End-Payor Plaintiffs point to statements by the California Supreme Court indicating that the state's antitrust law may be broader than the Sherman Act and that federal antitrust law is instructive rather than conclusive when construing the state's antitrust law. *Id.* But End-Payor Plaintiffs offer no argument that this broader state antitrust law reaches the conduct alleged here or that the other state antitrust laws under which they bring their claims are also broader than federal law and apply here. Indeed, for example, in bringing their claims for combination and conspiracy in restraint of trade against all Defendants, End-Payor Plaintiffs recount the same allegations as the DPP Complaint does and then merely list citations to the antitrust laws of twenty-seven states and the District of Columbia. EPP Compl. ¶ 334. They plead their other claims under the antitrust laws of various states in the same manner. But while they may "have *listed* claims under very many state laws, . . . they have not truly *pleaded* claims under those laws sufficient to show their entitlement to recovery under them, as required by Rule 8." *In re Aggrenox Antitrust Litig.*, 94 F. Supp. 3d at 255.

The same can be said about End-Payor Plaintiffs' remaining twenty-four claims for unfair or deceptive trade practices under state consumer-protection laws. The fundamental deficiency

with these claims is that they rely on the existence of anticompetitive conduct, which the Court has found insufficiently pleaded in the context of Direct Purchaser and Retailer Plaintiffs' federal antitrust claims. In their complaint, End-Payor Plaintiffs essentially attempt to rely on the factual foundation for federal antitrust claims—which in this case were found insufficient—and then "merely allege that those claims are also actionable under general consumer-protection laws." *In re Aggrenox Antitrust Litig.*, 94 F. Supp. 3d at 255. "But the plaintiffs cannot simply enumerate a long list of state-law claims for states where they might otherwise have no available antitrust recovery and rely on the defendants and the court to sort out whether or how those laws can act as surrogates for antitrust law." *Id.* at 255–56. End-Payor Plaintiffs have not provided a basis on which these claims survive when federal antitrust claims based on the same factual foundation fail. *See In re Actos End Payor Antitrust Litig.*, 2015 WL 5610752, at *28 ("Plaintiffs merely restate their antitrust allegations as separate consumer protection claims, providing no distinct factual basis for a violation of consumer protection law. This is insufficient to meet the Rule 8 pleading standard under *Twombly* and *Iqbal*.").

For these reasons, Defendants' motion to dismiss End-Payor Plaintiffs' Complaint for failure to state a claim is granted without prejudice to repleading the state-law claims in light of the dismissal of the federal antitrust claims. Accordingly, the Court need not consider the arguments from Nonresident Defendants' motion to dismiss the End-Payor Plaintiffs' Complaint's ninety-nine non-New York, state-law claims for lack of personal jurisdiction and Teva Israel's motion to dismiss the claims against it for lack of personal jurisdiction. *See ONY, Inc.*, 720 F.3d at 498 n.6; *Chevron Corp.*, 667 F.3d at 247 n.17.

CONCLUSION

Defendants' motion to dismiss the Direct Purchaser and Retailer Plaintiffs' Complaints for failure to state a claim is GRANTED, and the Direct Purchaser and Retailer Plaintiffs'

Complaints are DISMISSSED without prejudice to Direct Purchaser Plaintiffs and Retailer Plaintiffs filing amended complaints by February 22, 2022. Defendants' motion to dismiss the End-Payor Plaintiffs' Complaint for failure to state a claim is GRANTED, and the End-Payor Plaintiffs' Complaint is DISMISSED without prejudice to End-Payor Plaintiffs filing an amended complaint by February 22, 2022. Nonresident Defendants' motion to dismiss the End-Payor Plaintiffs' Complaint's ninety-nine non-New York, state-law claims for lack of personal jurisdiction and Teva Israel's motion to dismiss for lack of personal jurisdiction are DENIED without prejudice as moot.

The Clerk of Court is respectfully directed to close Dkt. Nos. 260, 265, 267, 271.

SO ORDERED.

Dated: February 2, 2022
New York, New York

LEWIS J. LIMAN
United States District Judge